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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

BARBARA SMITH and GARY SMITH, Plaintiffs, v. ETHICON, INC., ETHICON LLC and JOHNSON & JOHNSON, Defendants.	Civil No.: 3:20-cv-00851-MO **DEFENDANTS' WITNESS LIST AND WITNESS STATEMENTS**

Pursuant to the Court's Trial Management Order (Dkt. 193), Defendants Ethicon, Inc. and Johnson & Johnson ("Defendants") submit the following Witness List and Witness Statements.

PRELIMINARY STATEMENT AND OBJECTIONS TO PLAINTIFF'S WITNESS LIST AND WITNESS STATEMENTS

Plaintiff submitted her Witness List and Witness Statements on May 24, 2022 (Dkt. 240) ("PWL"). Initially, Plaintiff claimed in this case that she suffered injuries as a result of the implantation of two different devices manufactured by Ethicon: the Prolift device which is utilized to treat prolapse and the TVT-O device used to treat urinary incontinence. Subsequently, the Court dismissed Plaintiff's claims regarding the TVT-O device. (Dkt. 187). Further, in a meet and confer between Plaintiff and Defendant, Plaintiff represented that she would withdraw witnesses and testimony relevant to the TVT-O device. Then, on June 1, 2022, Plaintiff served her Third Supplemental Report of case-specific expert Daniel Elliott. In Dr. Elliott's newly filed report, he continues to link all of Plaintiff's claimed injuries to the Prolift device, not the TVT-O.

Despite these facts, Plaintiff lists witnesses whose testimony pertains solely or partly to the TVT line of products. Any testimony regarding the TVT line of products is irrelevant to the claims to be considered by the jury. Further, she lists witnesses who will testify regarding alleged complications that Plaintiff has not suffered as a result of the implantation of the Prolift device. Both categories of witness testimony are improper in this case as they are wholly irrelevant to the claims being made by Plaintiff in this particular case.

Defendants will file appropriate motions *in limine* to further detail why these witnesses and particular testimony are irrelevant and prejudicial to Defendants. While some of the witness testimony is not objectionable in their entirety, the two categories described above (TVT device testimony and complications not experienced by Plaintiff) should be excluded from their testimony. Defendants set forth below the particular witnesses with improper testimony for the Court's consideration. Defendants do not waive any additional motions *in limine* or objections that may be made as to the testimony offered by these witnesses at trial.

1. Laura Angelini – Plaintiff seeks to have Ms. Angelini testify regarding the risk of dyspareunia associated with Prolift mesh. *See* PWL at page 10. Plaintiff has not experienced dyspareunia as a result of her Prolift mesh implantation.
2. Axel Arnaud, M.D. – Plaintiff seeks to have Dr. Arnaud testify regarding the risks of dyspareunia, mesh shrinkage, mesh retraction, vaginal cavity distortion, interference with sexual function, and fibrotic bridging. *See* PWL at pages 11-12, 14-20. Plaintiff has not experienced any of these complications as a result of her Prolift mesh implantation.
3. Thomas Barbolt, Ph.D. – Plaintiff seeks to have Dr. Barbolt testify regarding the risks of shrinkage, contracture, entrapped nerves, and dyspareunia *See* PWL at pages 21-25. Plaintiff has not experienced any of these complications as a result of her Prolift mesh implantation.
4. Meng Chen, M.D. – Plaintiff seeks to have Dr. Chen testify regarding the TVT line of products. Dr. Chen will also testify regarding the risks of dyspareunia, sexual dysfunction, incontinence recurrence, vaginal pain due to sling implantation, local

irritation at the wound site, and mesh fraying. *See* PWL at pages 27-36. Plaintiff's claims involve only the Prolift device. The TVT line of products are not at issue in this case. Further, Plaintiff has not experienced any of these complications as a result of her Prolift mesh implantation.

5. Scott Ciarocca – Plaintiff seeks to have Mr. Ciarocca testify regarding the risks of mesh retraction, shrinkage, and contraction. *See* PWL at pages 38-40. Plaintiff has not experienced any of these complications as a result of her Prolift mesh implantation.
6. Jim Hart, M.D. – Plaintiff seeks to have Dr. Hart testify regarding the risks of mesh contraction, dyspareunia, pelvic pain, vaginal distortion, fibrosis, scar plate formation, punctures, and laceration. *See* PWL at pages 51-54. Plaintiff has not experienced any of these complications as a result of her Prolift mesh implantation.
7. Piet Hinoul, M.D. – Plaintiff seeks to have Dr. Hinoul testify regarding the risks of mesh contraction, shrinkage, vaginal destruction, lost sexual function, dyspareunia, retraction, fibrosis, scar plate formation, improper placement of Prolift, degraded mesh, and vaginal distortions. *See* PWL at pages 56-64. Plaintiff has not experienced any of these complications as a result of her Prolift mesh implantation.
8. Joerg Holste, Ph.D. – Plaintiff seeks to have Dr. Holste testify regarding the risks of contraction, shrinkage, fibrotic reaction and bridging, folded or wrinkled mesh, nerve entrapment, and scar plate formation. *See* PWL at pages 65-68. Plaintiff has not experienced any of these complications as a result of her Prolift mesh implantation.

9. Scott Jones – Plaintiff seeks to have Mr. Jones testify regarding the risks of scar tissue, bridging fibrosis, contraction, and dyspareunia. *See* PWL at pages 69-70. Plaintiff has not experienced any of these complications as a result of her Prolift mesh implantation.
10. Gene Kammerer – Plaintiff seeks to have Mr. Kammerer testify regarding the risks of mesh shrinkage, dyspareunia, contraction, scar formation, infection, and suture line dehiscence. *See* PWL at pages 71-75. Plaintiff has not experienced any of these complications as a result of her Prolift mesh implantation.
11. James Mittenthal – Plaintiff seeks to have Mr. Mittenthal testify regarding litigation holds issued by Ethicon for the TVT line of products. *See* PWL at pages 81, 84-84. Plaintiff's claims involve only the Prolift device. The TVT line of products are not at issue in this case.
12. Sean O'Bryan – Plaintiff seeks to have Mr. O'Bryan testify regarding the risks of mesh retraction, dyspareunia, risks to sexually active women, narrowing of the vaginal wall, mesh contraction, and pelvic pain. *See* PWL at pages 89-92. Plaintiff has not experienced any of these complications as a result of her Prolift mesh implantation.
13. Charlotte Owens, M.D. – Plaintiff seeks to have Dr. Owens testify regarding the risks of retraction, vaginal distortion, and dyspareunia. *See* PWL at pages 94-95. Plaintiff has not experienced any of these complications as a result of her Prolift mesh implantation.
14. Paul Parisi – Plaintiff seeks to have Mr. Parisi testify regarding alleged educational failures in training physicians to implant Prolift in a "tension free" manner. *See* PWL at pages 96-99. However, no physician or expert witness for Plaintiff has testified that

Plaintiff's Prolift was improperly implanted or that the tension applied to the device was improper.

15. David Robinson, M.D. – Plaintiff seeks to have Dr. Robinson testify regarding the risks of mesh contraction, and dyspareunia. *See* PWL at pages 104-106. Plaintiff has not experienced any of these complications as a result of her Prolift mesh implantation.
16. Rene Selman – Plaintiff seeks to have Mr. Selman testify regarding the risks of pelvic pain, dyspareunia, loss of coital functioning, vaginal shortening, destroyed vagina, and mesh contraction. *See* PWL at pages 109-110. Plaintiff has not experienced any of these complications as a result of her Prolift mesh implantation.
17. Clifford Volpe – Plaintiff seeks to have Mr. Volpe testify regarding the risks of bridging fibrosis and mesh shrinkage. *See* PWL at pages 122-123. Plaintiff has not experienced any of these complications as a result of her Prolift mesh implantation.
18. Mary Weisberg, M.D. – Plaintiff seeks to have Dr. Weisberg testify regarding the risks of dyspareunia and vaginal tissue sloughing. *See* PWL at page 124. Plaintiff has not experienced any of these complications as a result of her Prolift mesh implantation.

DEFENDANTS' WITNESS LIST AND STATEMENTS

Defendants respectfully request the right to supplement this list and substance of accompanying statements, if necessary, in response to any amendments served by Plaintiff as to her witness list and in response to any additional deposition testimony, medical records or supplemental expert reports produced by Plaintiff prior to trial. Defendants also respectfully request the right to call witnesses in response to unexpected trial testimony and request the right to examine any witness called by Plaintiff.

As noted above, Defendants maintain that Plaintiff has set forth testimony that is subject to exclusion per appropriate motions *in limine,* particularly regarding complications not claimed or experienced by Plaintiff and regarding the TVT line of products. Defendants' witness statements contain information that is necessary to rebut these issues should Defendants not succeed in excluding their content at trial. However, if Defendants are successful in removing these issues, Defendants' witness testimony will change appropriately.

I. Expert Witnesses

1. Dr. Doug Grier

Defendants' Designated Expert Witness – case in chief.

Live Testimony

Estimated Time of Testimony – 4 hours.

Substance of Testimony – *See* below and Defendants' Exhibit 1 (Grier 2/13/2017 Case-Specific Expert Report), Exhibit 2 (Grier 6/22/2019 Supplemental Case-Specific Expert Report), Exhibit 3 (Grier 7/26/2021 Second Supplemental Case-Specific Expert Report), Exhibit 4 (Grier Prolift General Expert Reports), Exhibit 5 (Grier TVT Device Family General Expert Reports), and Exhibit 6 (Grier Reliance Lists).

Dr. Douglas H. Grier, M.D. attended the University of Florida in Gainesville, Florida, graduating with a Bachelor of Science degree in Chemistry with High Honors in 1976. He attended medical school at George Washington University, graduating in 1982, and then did a surgical internship in 1982–1983 at the Portsmouth Naval Hospital in Portsmouth, Virginia. Following his internship, he was a urological residency at the Portsmouth Naval Hospital from 1984–1988. He served as Chief of Urology at Jacksonville Naval Hospital in 1990-91.

Prior to his residency, he served in Operation Urgent Fury in Grenada in October 1983 and as part of the Multinational Peacekeeping Force in Beirut, Lebanon in 1983–1984. After his residency, Dr. Grier served in Operation Desert Shield and Operation Desert Storm with the 1st Marine Division, stationed in Saudi Arabia and Kuwait in 1990–1991.

Dr. Grier is the President of the Medical Staff at Swedish/Edmonds Hospital in Edmonds, Washington. He also serves as the Chair of Swedish Hospital's Medical Quality Oversight Committee, Chair of the Credentials Committee, Treasurer of the Medical Staff for the Swedish Hospital System, and as a member of the Executive Committee at Swedish Hospital.

Dr. Grier became a Diplomate of the American Board of Urology in 1990 and was recertified in 2010. He is an active member of the American Urological Association, the Washington State Medical Association, the Northwest Urological Society, the Washington State Urology Society, the King County Medical Society, the American Association of Clinical Urologists, the Society of Urodynamics Female Pelvic Medicine & Urogenital Reconstruction, and the International Continence Society.

Dr. Grier served as a faculty member at the Ethicon Endosurgical Institute, and as a National Preceptor for Gynecare products, conducting over 300 courses for advanced surgical training of physicians for conditions such as stress urinary incontinence and pelvic organ prolapse. He has lectured to pelvic floor surgeons throughout the United States, Canada, Europe, and China and performed research in the field of incontinence and bladder disorders, contributing to studies on the use of TVT abdominal guides, and the TVT world registry

published in the Journal of Urology in 2011. He was also an investigator in an FDA trial of a pelvic nerve stimulator for the treatment of urge incontinence.

Dr. Grier has a special focus in female pelvic medicine and surgery. Over the course of his career, Dr. Grier has performed various types of native tissue surgery and surgery utilizing mesh, including Ethicon's TVT and TVT-O, TVT-Abbrevo, and TVT-Secur mid-urethral slings, AMS Monarch, Uretex by Bard, Vesica In situ sling, Stamey cystourethropexy, MMK, and Burch procedures. He's also performed robotic sacrocolpopexies, open abdominal sacrocolpopexies, and various types of native tissue surgeries and surgeries utilizing mesh—including the Prolift device—to treat pelvic organ prolapse.

Dr. Grier will testify regarding the historical background of the surgical use of mesh, the development of tension-free vaginal tape using prolene mesh, the TVT, the TVT-O, the TVT-Exact, the TVT-Abbrevo, instructions for use for these devices, and the usefulness, desirability, and safety of these devices. Dr. Grier will testify regarding the development of the Prolift device, the safety and efficacy of Gynemesh PS and the Prolift device, instructions for use for these devices, and the usefulness, desirability and safety of the Prolift device.

Dr. Grier will testify about Ms. Barbara Smith's relevant medical history including, but not limited to, her three vaginal births, her smoking history, her history with obesity, depression, irritable bowel syndrome, chronic back pain, fibromyalgia, hypertension, diverticular disease, rectal laxity, and anxiety. Dr. Grier will testify about Ms. Smith's relevant past surgical history including, but not limited to, an ovarian cyst removal in 1975, a bladder repair and total abdominal hysterectomy in 1981, and colonoscopy in 1999.

Dr. Grier will testify regarding the frequency of urinary incontinence and pelvic organ prolapse in women, and the risk factors, such as smoking, obesity, menopause, pregnancy and childbirth, chronic constipation and heavy lifting, race, age, congenital factors, and hysterectomy. Dr. Grier will testify regarding the treatment options for stress urinary incontinence and pelvic organ prolapse, including nonsurgical and surgical options.

Dr. Grier will testify about Ms. Smith's 2006 Anterior and Posterior repair with Prolift and a TVT-O mid-urethral sling implanted by Dr. Peter Zenthoefer. Dr. Grier will testify that these devices are safe and effective, have a positive benefit-to-risk profile, and are more effective in treating prolapse and incontinence than alternative treatments would have been. Further, Dr. Grier will testify that the development and utilization of synthetic meshes for repair of vaginal prolapse over the past 25+ years occurred because native tissue repairs have an unacceptably high failure rate, but that all stress incontinence and prolapse surgeries carry a risk of scarring, adhesion formation, infection, exposure or erosion pain, pelvic pain, dyspareunia, bowel or bladder dysfunction, and failure of the operation. Ultimately, Dr. Grier will testify that Ms. Smiths' course is not indicative of a defect in the Prolift or the TVT-O.

Dr. Grier will testify regarding Ms. Smith's 2007 cystoscopy, which showed no mesh anywhere inside the bladder and was unremarkable. Dr. Grier will testify regarding Ms. Smith's 2011 cystourethroscopy, which showed no mesh erosions or lesions. Dr. Grier will testify regarding Ms. Smith's 2011 excision of mesh and tissue and cystoscopy. Dr. Grier will testify regarding Ms. Smith's 2012 diagnostic laparoscopy, cystoscopy with placement of ureteral catheters, exploratory laparotomy with lysis of adhesions, abdominal drainage of pelvic abscess, vaginal excision of mesh, and cystourethroscopy. Dr. Grier will testify

regarding Ms. Smith's unsuccessful 2019 cystoscopic removal. Dr. Grier will testify regarding Ms. Smith's 2020 bladder mesh excision, which was prolonged 2 hours by technical difficulties, in which the area of mesh exposure was excised using a laser, which is directly contributory to the formation of a vesicovaginal fistula developing post operatively. Dr. Grier will testify regarding Ms. Smith's 2020 cystoscopy, which revealed no evidence of bladder exposed mesh but a pinpoint vesicovaginal fistula, which repair of was placed on hold due to Ms. Smith's continuous tobacco usage. Dr. Grier will testify regarding Ms. Smith's 2020 vaginal approach vesicovaginal fistula repair.

Dr. Grier will testify regarding his observations and findings at the two independent medical examinations of Ms. Smith on 2/1/2017 and 11/17/2020. Dr. Grier will testify that Ms. Smith's recurrent urinary problems, pelvic pain, erosion, and infections are not attributable to any alleged defects in the Prolift Total or TVT-O implants. Dr. Grier will testify that these devices are state of the art.

Dr. Grier will testify that Ms. Smith's urinary incontinence existed for years preoperatively and the TVT-O is not indicated or expected to treat urgency/frequency, bladder detrusor overactivity, or to prevent recurrent urinary tract infections. He will testify that Ms. Smith's persistent voiding dysfunction is unrelated to her previous TVT-O and Prolift surgery.

Dr. Grier will testify that Ms. Smith has multiple factors contributing to her pelvic pain, including, but not limited to, a previous pelvic surgery with a hysterectomy and obstetrical scarring with an ongoing history of tobacco usage. He will testify that Ms. Smith has irritable bowel syndrome and chronic fibromyalgia which commonly causes pain flairs after surgical procedures and is exacerbated by stress. He will testify that the most likely cause of her acute

suprapubic and pelvic pain is active chronic cystitis, which has not been treated and that Ms. Smith has not been provided chronic antibiotic urinary suppression to sterilize her urine and allow the bladder mucosa to heal over time.

Dr. Grier will testify that Ms. Smith's exposure issues stem from a wound healing problem that was complicated by her prior surgical procedures, including a seven-hour long hysterectomy due to severe adhesive disease, and other conditions, including vaginal atrophy for which she non-compliantly did not use prescribed estrogen therapy, obstetric scarring, obesity, hyperlipidemia, and ongoing history of smoking.

Dr. Grier will testify that when acute bladder infections are not treated and allowed to persist over weeks, months, and perhaps in Ms. Smith's case over years, bacteria become incorporated within the epithelial lining of the bladder creating chronic cystitis, and chronic irritative voiding symptoms with the possibility of systemic infections including pyelonephritis. He will testify that Ms. Smith's urinary infections are not caused by the Prolift mesh but rather due to untreated chronic bladder infections.

Dr. Grier will testify that where true bladder erosions occur, they are not caused by any alleged defect in the Prolift or TVT-O devices, but typically occur due to either surgeon or patient factors, or a combination of the two. Here, Ms. Smith's smoking history, more likely than not, contributed to her erosion. Dr. Grier will testify that any predisposing susceptibility to recurrence of mesh erosion is indicative of her poor tissue quality resulting from smoking, prior surgical history, and other conditions, and not caused by her mesh implants.

Dr. Grier will testify regarding the studies referenced in his report and supplemental reports.

Dr. Grier will testify that the IFU for the Prolift device was appropriate and allowed surgeons to use the device safely for its intended purposes.

2. Dr. Christina Pramudji

Defendants' Designated Expert Witness – case in chief.

Live Testimony

Estimated Time of Testimony – 4 hours.

Substance of Testimony – *See* below and Defendants' Exhibit 7 (Pramudji Gynemesh PS & Prolift General Expert Report), Exhibit 8 (Pramudji TVT & TVT-O General Expert Report), and Exhibit 9 (Pramudji Reliance Lists).

Dr. Christina K. Pramudji, M.D. is a board-certified urologist, with a subspecialty board certification of Pelvic Floor Medicine and Reconstructive Surgery. She received a Bachelor of Science in Chemical Engineering from Georgia Institute of Technology (Georgia Tech) *cum laude,* which included a Chemical Engineering Internship at the University of London. She received her M.D. degree from the University of Alabama School of Medicine in Birmingham in 1996. Then, she completed a general surgery and urology residency at Baylor College of Medicine in Houston, Texas, where she received extensive training in pelvic floor medicine and surgery. During this training, Dr. Pramudji performed various surgeries to treat urinary incontinence and other pelvic and urologic conditions and disorders. Since then she has been in private practice for over 12 years and the focus of her practice is female urology and pelvic floor medicine.

Dr. Pramudji has a vast experience with prolapse surgery, having performed well over 1000 surgeries. She has used tailored Gynemesh PS as well as performed about 450 Prolift

surgeries, 75 surgeries with Prosima, numerous other transvaginal mesh repairs for prolapse, native tissue repairs and hundreds of abdominal sacrocolpopexies including open and robotic sacrocolpopexies with mesh including Gynemesh PS. She was trained on the Prolift, Prosima, and Ethicon prolapse devices and was a proctor teaching them to surgeons across numerous states as well as at national conferences such as the AUA. She also has a vast experience with mid-urethral slings, having performed over 1,000 sling procedures from various manufacturers and of various approaches She is very familiar with the Ethicon TVT and TVT-O devices, having been trained in their use and having surgically placed them in hundreds of procedures. She has been a consultant for Ethicon and Boston Scientific in sling development and has extensive mesh experience in over 600 cases and has managed mesh complications as well. Her urologic practice is dedicated solely to female urology, pelvic medicine, and reconstructive surgery.

Dr. Pramudji will testify that pelvic organ prolapse and urinary incontinence, including stress and urge incontinence, are common conditions in women with many risk factors. She will testify that pelvic organ prolapse and incontinence can be very distressing and burdensome to women and can cause adverse effects on women physically, mentally, and socially affecting quality of life and relationships. She will testify that urinary incontinence can be treated with lifestyle changes and behavioral therapy, non-surgical options and surgery. She will testify that pelvic organ prolapse is usually treated with a pessary, a non-surgical option, or with surgery. She will testify that more conservative efforts to treat incontinence and prolapse may not be a suitable option for some women and they may not always provide relief. She will

testify that many women who try more conservative measures, such as a pessary, will discontinue the therapy.

Dr. Pramudji will testify that surgery for prolapse is common, frequently involving various prolapse procedures, and is also frequently combined with other procedures, such as hysterectomy and incontinence surgery. She will testify that pelvic floor reconstruction surgery for prolapse can be and is frequently categorized by route into the abdominal or vaginal approach, with the vaginal route most often employed. Further, that native tissue repairs are most often done vaginally. She will testify that some examples include colporrhaphy, paravaginal repair, and sacrospinous or uterosacral ligament suspensions. Dr. Pramudji will testify that surgical mesh is employed for both the abdominal (sacrocolpopexy) and vaginal approaches; the abdominal approach is more morbid and extensive, leading to higher significant complication rates, blood loss, postoperative discomfort, length of hospital stay and cost. She will testify that pelvic floor reconstruction surgery for prolapse can also be further divided by the type of prolapse, such as cystocele, rectocele, vault prolapse, or a combination of these, and as stated above multiple procedures are sometimes employed to treat site-specific defects.

Dr. Pramudji will testify that synthetic mesh has been used to treat prolapse since the 1960s because the various native tissue repairs are associated with higher rates of failure and surgeons have continually sought better options for their armamentarium. Further, that over the past 50 years, pelvic floor surgeons have employed surgical mesh for abdominal sacrocolpopexy and for vaginal procedures, such as the use of free cut mesh, transvaginal mesh kits or the reinforcement of colporrhaphy with mesh.

Dr. Pramudji will testify that mesh made of monofilament, large pore polypropylene, like Gynemesh PS which is also used in the Prolift and Prosima devices and sacrocolpopexy, has been most commonly used and is the standard for both the abdominal and vaginal approaches to pelvic organ prolapse repair. She will testify that the mesh is made of the same polypropylene as the Prolene suture, which can be used in vaginal vault prolapse procedures like the sacrospinous or uterosacral ligament suspension surgeries. She will testify that clinical data shows that the monofilament, large pore polypropylene like Gynemesh PS allows for adequate tissue ingrowth and is not associated with a significantly increased risk of infection over that generally associated with prolapse surgery and vaginal surgery, which is consistent with her clinical experience in hundreds of women. She will testify that the data in women does not support that Gynemesh PS degrades, as reoperation rates for recurrence are low, cure rates and satisfaction is high, and complication rates are not consistent with degradation or that if it did degrade, it would have a clinically significant effect, and that she has not seen evidence of mesh degradation in her clinical practice. She will testify that Gynemesh PS has been the most studied mesh in pelvic reconstructive surgery, with numerous randomized controlled trials and over 100 studies which demonstrate that Gynemesh PS, when used itself or in the Prolift and Prosima devices, is effective, safe and useful. No other mesh has been studied nearly to the degree of Gynemesh PS and in this regard it surpasses all industry standards and is state of the art. She will testify that it has proven efficacy and safety in both the abdominal and vaginal applications for treating POP.

She will testify that other meshes like PVDF, Dynamesh, and Vypro have not been demonstrated to be more efficacious or safer based on the reliable scientific literature nor have

they been studied in the prolapse application like Gynemesh PS. She will testify that Vypro when studied for prolapse was found to be not well tolerated. She will testify that studies of Ultrapro show similar rates of mesh exposure and dyspareunia and change in sexual function as Gynemesh PS and Prolift and it has not been demonstrated to be more efficacious.

Dr. Pramudji will testify that Gynemesh PS and Prolift have a positive benefit-to-risk profile, and overall, the Gynemesh PS and Prolift provide better anatomic support than native tissue repairs and subjective satisfaction is very high. She will testify that improvements in quality of life following are also frequently seen and reported in the medical literature and more recent data show improvements in quality of life that are statistically significantly higher than native tissue repair. She will testify that the Prolift is minimally invasive compared to the abdominal sacrocolpopexy and less morbid.

Further, Dr. Pramudji will testify that Prosima, which also uses Gynemesh PS, has a positive benefit-to-risk profile, and overall, the Prosima provides effective treatment of anatomic defects and subjective satisfaction with Prosima is very high. She will testify that improvements in quality of life following Prosima are frequently seen and reported in the medical literature and that the Prosima is minimally invasive compared to the abdominal sacrocolpopexy and less morbid. She will testify that it is also potentially less invasive than trocar based mesh kits and that it is indicated for stage 2 and 3 prolapse.

Dr. Pramudji will testify that all surgeries to treat pelvic organ prolapse have risks, and that like Gynemesh PS, Prolift and Prosima, other prolapse and vaginal surgeries are performed in the pelvis and utilize surgical instruments, like trocars, Stamey needles, Capio needle holders, and other needle holders, in the surgical field. She will testify that potential risks of

operating in this area are well described to surgeons during training, in medical textbooks, and in the medical literature, and are well-known risks. The same is true for the tensioning of sutures, grafts, and mesh whether made of synthetic, animal or native tissue, and the potential complications such as contraction of the scar tissue or pain. She will testify that tissue contraction, pain, pelvic pain, and dyspareunia can occur with any incontinence, prolapse surgery and vaginal surgery, such as concomitant posterior colporrhaphy, native tissue vault suspensions, hysterectomy and lysis of adhesions and that these risks are well known and described in the literature, as well as taught to surgeons in their education and training. She will testify that clinical data does not show a statistically significant higher risk of de novo dyspareunia, de novo pelvic or vaginal pain, or change in sexual function, or change in vaginal length with Gynemesh PS, Prolift or Prosima compared to native tissue prolapse repair.

She will testify that mesh exposure/erosion is the only unique risk when using Gynemesh PS and synthetic mesh, and in the case of Gynemesh PS it can be treated conservatively or easily treated in an outpatient or inpatient procedure in the majority of cases. She will testify that suture and graft erosion and other wound complications can occur with non-mesh prolapse surgeries at similar and higher rates.

She will testify that Gynemesh PS, Prolift and Prosima are not defective in their designs, and the devices have utility and provide a durable repair. Moreover, that the risks with Gynemesh PS, Prolift and Prosima are adequately described in the IFU and professional education materials. She will testify that the Patient Brochures also provides adequate information to a lay person to discuss the potential options and the device with her surgeon, but it is not meant to replace the surgeon-to-patient dialogue and consenting process. She will

testify that the Professional Education, which is recommended and incorporated into the IFU, is industry leading and above and beyond the standard of care, and discusses implantation, complications and complication management as well.

In the event that the Court does not exclude testimony regarding the TVT line of devices, Dr. Pramudji will be prepared to testify as follows. Dr. Pramudji has a vast experience with mid-urethral slings, having performed over 1000 sling procedures from various manufacturers and of various approaches. Dr. Pramudji also has vast experience with prolapse surgery, having performed well over 1000 surgeries. She has used tailored Gynemesh PS as well as about 450 Prolift surgeries, 75 surgeries with Prosima, numerous other transvaginal mesh repairs for prolapse, native tissue repairs and hundreds of abdominal sacrocolpopexies including open and robotic sacrocolpopexies with mesh including Gynemesh PS. She was trained on the Prolift, Prosima, and Ethicon prolapse devices and was a proctor teaching them to surgeons across numerous states as well as at national conferences such as the AUA. She is also very familiar with the Ethicon TVT and TVT-O devices, having been trained in their use and having surgically placed them in hundreds of procedures. She has been a consultant for Ethicon and Boston Scientific in sling development and has extensive mesh experience in over 600 cases and has managed mesh complications as well. She has an interest in bladder and pelvic floor surgery, so when she realized that the majority of her practice involved women with those sorts of problems, she decided to make it the major focus of her practice.

Dr. Pramudji will testify that urinary incontinence, including stress and urge incontinence, are common conditions in women with many risk factors, and more specifically stress urinary incontinence. She will testify that incontinence can be very distressing and

burdensome to women and can cause adverse effects on women physically, mentally, and socially affecting quality of life and relationships. She will testify that stress urinary incontinence can be treated with lifestyle changes and behavioral therapy, non-surgical options and surgery. She will testify that more conservative efforts to treat incontinence may not be a suitable option for some women and they may not always provide relief. She will testify that many women who try more conservative measures will discontinue the therapy.

Dr. Pramudji will testify that surgery for stress urinary incontinence has been shown to be the most definitive treatment. These surgeries include the Burch colposuspension, native/biologic tissue slings and most often, synthetic slings made of monofilament, large pore polypropylene like that used in TVT and TVT-O. She will testify that the clinical data shows that the TVT and TVT-O Type 1 macroporous Prolene polypropylene mesh is biocompatible, has a minimal inflammatory response, allows for adequate tissue ingrowth and is not associated with a significantly increased risk of infection over that generally associated with SUI and vaginal surgery, which is consistent with her clinical experience in hundreds of women. She will testify that the data in women does not support that the TVT and TVT-O mesh is cytotoxic, causes an adverse inflammatory response, sarcoma or cancer, or that the way the edges are cut has any clinically significant effect. She will testify that the data in women also does not support that the TVT and TVT-O mesh degrades, or that, if it did, it would have a clinically significant effect, and she has not seen evidence of mesh degradation in her clinical practice.

Dr. Pramudji will testify that the TVT and TVT-O have a positive benefit to risk profile, more specifically a better benefit/risk profile than the Burch and native tissue slings. She will

testify that the TVT and TVT-O have great utility to surgeons and their patients and extensive data exist which supports the TVT and TVT-O and shows that they are minimally invasive and less invasive than the Burch and native tissue slings. She will testify regarding the advantages of these devices, such as shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization, faster recovery, and reduced complications, including voiding dysfunction. She will testify that polypropylene mesh has been used for decades, and that TVT and TVT-O are safe and effective surgical options for the treatment of SUI.

Dr. Pramudji will testify that the TVT and TVT-O slings have been extensively studied in over 100 Randomized Controlled Trials (RCTs) and hundreds of other studies. Also, that the TVT and TVT-O have been extensively used in clinical practice by urologists, gynecologists, and urogynecologists and taught to doctors during residency and fellowship because they are recognized as suitable surgical options to treat stress urinary incontinence. She will testify that the TVT and the TVT-O are the Gold Standard and standard of care for treating stress urinary incontinence and that the overall cure and improvement rates are generally in the 80-95% range with significant improvements in symptoms and quality of life. She will testify that complications are infrequent and manageable, that the rate of mesh exposure is 1-2%, voiding dysfunction and retention is about 1-4%, complications requiring surgical management occur at a rate of 2-4%, and that dyspareunia and pain are also rare (<1%) and occur more often with the Burch and native tissue slings. She will testify that the risk of surgery due to mesh exposure or erosion, voiding dysfunction and retention, and pain is rare even out to 10-17 years follow up according to high level data. She will testify that the need for a second revision is very uncommon according to the reliable scientific data. She will

testify that case reports and case series are of limited value and do not address the incidence of complications or primary and secondary management.

Dr. Pramudji will testify that the TVT and TVT-O have been studied and evaluated by members of the pertinent medical and surgical organizations, such as the American Urologic Association (AUA), Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU), American Urogynecologic Society (AUGS), International Continence Society (ICS), National Institute for Health and Care Excellence (NICE), Society of Gynecologic Surgeons (SGS), International Urogynecological Association (IUGA), and the European Association of Urology (EAU), and are found to be safe and effective and widely recognized as the Gold Standard, standard of care, and first line and suitable surgical option to treat stress urinary incontinence.

Dr. Pramudji will testify that all surgeries to treat stress urinary incontinence have risks. She will testify that, like the TVT and TVT-O, other SUI surgeries are performed in the pelvis and utilize surgical instruments, like Stamey needles, in the surgical field and the potential risks of operating in this area are well described to surgeons during training, in medical textbooks, and in the medical literature, and are well known risks. Also, that the same is true for the tensioning of sutures as well as slings, whether made of synthetic or animal or native tissue, and the potential complications such as voiding dysfunction. She will testify that pain, pelvic pain, and dyspareunia can occur with any SUI surgery and vaginal surgery, are well known and described in the literature, as well as taught to surgeons in their education and training. She will testify that dyspareunia and sexual dysfunction that preexists in women can also be cured or improve following TVT or TVT-O placement. She will testify that mesh

exposure/erosion is the only unique risk when using the TVT and TVT-O and it is uncommon and can be easily treated in the majority of cases. Further, she will testify that suture and sling erosion and wound complications can occur with non-TVT/TVT-O SUI surgeries. Ultimately, she will testify that the TVT and TVT-O are not defective in their design and from her perspective as a surgeon, the risks are adequately described in the IFU and professional education materials.

Dr. Pramudji will testify that other devices, such as PVDF, Prolene Soft, Vypro or Ultrapro that have been used in hernia and prolapse repair, have no similar breadth and length of clinical data in SUI patients than the TVT or TVT-O. She will testify that these other devices have inadequate data showing that these meshes would work long term in the design of the TVT or TVT-O, which have long term data. She will testify that these meshes have not been studied to treat SUI in women like TVT and TVT-O.

3. **Steve MacLean**

Defendants' Designated Expert Witness – case in chief.

Live Testimony

Estimated Time of Testimony – 3 hours.

Substance of Testimony – *See* below and Defendants' Exhibit 10 (MacLean General Expert

Reports) and Exhibit 11 (MacLean Reliance Lists).

Dr. MacLean's research is focused on the chemical and physical behavior of polymeric materials in end-use applications. His specialties include part design and analysis, failure analysis,

material specification, testing and patent analysis. He has studied various polymer failure mechanisms including stress overload, creep rupture, fatigue, environmental stress cracking, delamination and weathering. Throughout his career he has evaluated the suitability and performance of polymeric materials in end-use applications, including specifically, for the medical device industry. Dr. MacLean assists clients in assessing risk in all stages of product life including product development, reliability testing and long-term field performance.

Dr. MacLean is well-versed in product recall investigations led by the Consumer Product Safety Commission (CPSC), the National Highway Traffic Safety Administration (NHTSA) and the National Transportation Safety Board (NTSB). He is familiar with the processes of each federal agency regarding the investigation, analysis, and remedies of underperforming products and components. Dr. MacLean is also familiar with testing and material standards published by ASTM International, International Standards Organization (ISO), Underwriters Laboratories (UL), International Electrotechnical Commission (IEC) and the Society of Automotive Engineers (SAE).

Over the past 20 years, Dr. MacLean has worked on numerous projects related to polymer and composite manufacturing processes including injection molding, compression molding, blow

molding, rotational molding, extrusion, fiber spinning, thermoforming, and laminating. In addition, he has investigated failures related to secondary operations used throughout the plastics industry such as metallic plating, adhesive joining, painting and welding.

Prior to joining Exponent Failure Analysis Associates, Inc. (“Exponent”), Dr. MacLean spent 16 years in the plastics industry at General Electric (GE) Plastics and SABIC Innovative

Plastics where he held several technical and leadership positions of increasing responsibility. He was routinely involved in material selection and testing for high-demand applications, product safety assessments, failure analysis, and intellectual property analysis.

While at GE and SABIC, Dr. MacLean worked with numerous medical device companies on material development, material specification, design and manufacturing for a wide variety of medical device applications. These efforts included, inter alia, developing and implementing tests related to the bulk physical properties of polymeric materials specified in said devices as well as material formulation development to meet unique device requirements that could not be met with off-the-shelf grades of resin. Formulation development often included the selection and refinement of base polymers or alloys, molecular weight, additives, stabilizers, processing aides, lubricants, colorants and inorganic fibers and fillers. In addition to proactive design and material selection assistance, Dr. MacLean have worked on hundreds of product safety assessments and failure analyses involving polymeric materials, many of which were performed on medical devices and components.

In his prior role as Director of Global Agency Relations and Product Safety at GE/SABIC, part of Dr. MacLean's leadership responsibilities included being an active member of the business' Healthcare Resins Advisory Board. The board developed internal processes and standards for the specification, use and sale of GE/SABIC resins in medical device applications. These efforts included ensuring that commercial resin grades within the GE/SABIC healthcare portfolio were assessed for biocompatibility using industry accepted test protocols such as United States Pharmacopeia (USP) Class VI, Tripartite Biocompatibility Guidance, or ISO 10993 Biological Evaluation of Medical Devices standards. For the past

several decades, the latter two standards have been supported by the Food and Drug Administration (FDA) and commonly employed to assess the potential for cytotoxicity, hemolysis, pyrogenicity, sensitization issues, among other biological effects, when the human body is exposed to foreign materials. In addition, the board also ensured that "good manufacturing processes" were globally implemented to maximize the purity levels of all compounded materials within the healthcare resin portfolio.

Over the past several years, Dr. MacLean has been scientifically researching the chemical, physical and environmental behavior of implanted polypropylene-based surgical mesh. During this time, he has reviewed and synthesized hundreds of journal articles, authoritative texts and other technical treatises to guide his understanding and opinions regarding changes to polypropylene- based mesh after implantation in the body. In addition to reviewing the public literature, Dr. MacLean has performed several polypropylene mesh-related scientific studies. These investigations have included visual, optical microscopy, and scanning electron microscopy examinations of exemplar and explanted mesh, histological staining of exemplar and intentionally oxidized exemplar mesh, chemical analysis of the mesh material, and a multistep cleaning process designed to remove biological material from the surface of explanted mesh. As a result of his research, Dr. MacLean has published and presented his findings with the Division of Medical Plastics of the Society of Plastics Engineers in 2016.[1]

[1] Benight S, MacLean S, Garcia M, Moll, J. "Microscopy of intentionally oxidized polypropylene-based mesh material." Proceedings, ANTEC Medical Plastics Division, 2016.

Dr. MacLean earned his B.S. (1993) and M.E. (1997) in Mechanical Engineering from Rensselaer Polytechnic Institute. He also earned his M.S. in Materials Science and Engineering from Rochester Institute of Technology in 2001 and his Ph.D. in Materials Science from University of Rochester from 2007. He is currently a Principal Engineer in the Polymer Science and Materials Chemistry Practice at Exponent. Dr. MacLean is a registered Professional Engineer in New York and Maryland, a Senior Member of the Society of Plastics Engineers (SPE), and a board member of SPE's Failure Analysis and Prevention Special Interest Group. His expertise and experience include the chemical and physical behavior of polymeric materials in end-use applications, specifically in the evaluation of polymeric components in product safety assessments and product failure analysis.

Dr. MacLean's testimony at trial will include the following:

- Chemical structure of polypropylene
- Crystallinity
- Molecular weight
- Thermal properties of polypropylene
- Manufacturing of polypropylene resins
- Processing of polypropylene fibers
- Polypropylene applications
- Oxidation of polypropylene
- Formaldehyde-protein crosslinking
- Composition of prolene
- Prolene biocompatibility

- Introduction to surgical mesh
- Current surgical mesh materials
- Suture and mesh literature review
- Ethicon's investigation: microcrack committee investigation; microscopy; mechanical testing; melting point analysis; FTIR analysis; Seven Year Dog Study
- Exponent's analysis of cleaned explanted mesh
- Artifacts in microtome processing
- Exponent investigation into staining of intentionally oxidized prolene mesh: hematoxylin and eosin (H&E) stain; experimental investigation of the capacity of prolene and oxidized prolene to accept H&E stain; validation of microscopy experiments
- Dr. MacLean will also provide testimony rebutting Plaintiff's expert Dr. Uwe Klinge.

Based on his analysis, education, training, and experience in mechanics of materials, polymer science, materials chemistry, and mechanical engineering, Dr. MacLean has formed the following opinions to a reasonable degree of engineering and scientific certainty:

- Based on the tensile testing performed by Ethicon during its Seven Year Dog Study, it has been conclusively determined that the PROLENE material becomes more ductile, tougher, and less stiff while implanted.
- Based on the molecular weight analyses performed by Ethicon during the seven year dog study, the PROLENE material is not suffering from any quantifiable degradation while *in vivo*.

- Based on its historical use, long-term testing performed by Ethicon, and retention of bulk physical properties while in vivo, PROLENE is a suitable material for implanted mesh devices.

- No reliable scientific evidence has been presented to decisively determine that the "bark layer" is comprised of PROLENE. H&E staining, polarized light microscopy, and melting point analysis are not accepted methods used in the conclusive chemical identification of polypropylene-based materials.

- Plaintiff's experts' assertion that the PROLENE mesh material has degraded *in vivo* is based solely on an observed reduction in melting point as well as visual and microscopic observations of "bark micro-cracking," which is contrary to scientific principles.

- Plaintiff's experts' assertion that the PROLENE mesh material has become brittle is also solely based on visual and microscopic observations of "bark micro-cracking," not on mechanical testing, and is contrary to the scientific findings from Ethicon's Seven Year Dog Study.

- Plaintiff's experts' assertion that PROLENE becomes stiffer (less pliable) and resists tissue contraction causing inflammation/pain is based on observed "bark micro-cracking" and tactile feel (a highly subjective assessment). No standardized mechanical testing has been performed to support this subjective assertion. This assertion is contradicted by the mechanical property testing performed by Ethicon, and the fundamental principles of mechanics of materials.

- The images presented in the Plaintiff's expert report[2] of "freshly excised" cracked PROLENE mesh that has reportedly never been exposed to formalin need to be tempered with Ethicon's findings that exposure to air alone can cause a saline-preserved "wet" explanted fiber to crack in a relatively short period of time. Moreover, the possibility cannot be excluded that mechanical forces applied to the mesh during explanation did not contribute, and/or cause the observed cracking.

- There has been no testing performed or scientific literature cited to support the belief that degraded PROLENE is capable of being histologically stained with H&E stain. Therefore, any related conclusions, are scientifically unreliable.

- Through a series of controlled oxidation, microtoming, and microscopy experiments, Exponent demonstrated that oxidized PROLENE mesh fibers and sutures do not become stained with H&E dyes. This fact is supported by polymer science first principles, given that PROLENE does not possess chemical groups amenable to binding with the H&E stain molecules.

- Artifacts can be easily introduced during sample preparation, sectioning, staining, and imaging, giving the appearance of darkened outer layers.

- A brittle outer layer will not contribute to the stiffness of the mesh if it is thin, cracked, and discontinuous. Plaintiff's expert's Dr. opinion that a thin, cracked, porous outer layer causes an increase in mesh stiffness is not consistent with first principles of polymer science and contradicted by the measured modulus data from Ethicon's seven year dog study.

[2] Iakovlev MDL Consolidated Case Report dated 8-24-2015, pp. 83–84.

- Upon thorough cleaning, the presence of extrusion die lines underneath the crust layer of explanted mesh has been confirmed. Had the original fiber surface suffered from *in vivo* oxidation and formed an outer crust layer, die lines would not exist after cleaning.

- Based on the microscopic examination of intentionally oxidized mesh after cleaning, the cleaning process does not remove oxidized material from the surface of the PROLENE mesh.

- Biological elements, native to the *in vivo* environment and foreign to the PROLENE resin formulation, were conclusively identified within the crust layer of explanted mesh. As such, the crust is biological in nature and not degraded PROLENE.

- Plaintiff's expert, Dr. Klinge, opined that antioxidants, DLTDP and Santonox R, leach from PROLENE with time *in vivo*, but failed to perform his own experiments and instead relied on a study presented in an expert report authored by Dr. Jordi in 2013.[3] In this study, Dr. Jordi used liquid chromatography-mass spectrometry (LC-MS) to attempt to show that antioxidants can leach from PROLENE. LC-MS is an experimental technique that, when correctly employed, can be utilized to determine the concentration of various extractable components in a polymer. Dr. Jordi performed this analysis on explants as well as on various control samples in an attempt to determine the concentrations of DLTDP and Santonox R in each specimen. In this study, during sample preparation, Dr. Jordi attempted to mechanically remove attached biological material using forceps, however, complete tissue removal was never confirmed prior to his LC-MS analysis. Dr. Jordi then made quantitative conclusions

[3] Jordi Lewis Report dated 10-12-13.

on the amount of antioxidants in the explanted mesh based on the original mass of the specimen. Without verifying that the measured mass is solely from the mesh and not in part from residual biologic material, any conclusions regarding the levels of antioxidants DLTDP and Santonox R present are erroneous.

- Furthermore, Dr. Jordi's control experiments leave much to be desired. His formalin-treated mesh controls were only exposed for a fraction of the length of time the explants were exposed to formalin. As a result, this control is invalid and it is impossible to eliminate the possibility that Santonox R and DLTDP were drawn out of the explants during their extended storage in formalin. In fact, Dr. Jordi showed in his analysis that Santonox R is easily extracted from PROLENE after exposure to formalin for only 48 hours at 60°C. Therefore, any conclusions relating to the concentration of antioxidants in explanted mesh while in vivo based on Dr. Jordi's LC-MS data are unfounded.

4. **Timothy Ulatowski**[4]

Defendants' Designated Expert Witness – case in chief.

Live Testimony

Estimated Time of Testimony – 3 hours.

[4] Defendants previously withdrew Mr. Ulatowski as an expert witness, but as indicated at the April 26, 2022 hearing on Plaintiff's motion to allow amendment to add a punitive damages claim, Defendants anticipate potentially calling Mr. Ulatowski to testify regarding regulatory issues presented by Plaintiff's punitive damages claim. Defendants will withdraw another expert if they move to allow Mr. Ulatowski's testimony.

Substance of Testimony – *See* below and Defendants' Exhibit 12 (Ulatowski Prolift General Expert Reports), Exhibit 13 (Ulatowski TVT & TVT-O General Expert Reports), and Exhibit 14 (Ulatowski Reliance Lists).

Timothy A. Ulatowski is a consultant on matters concerning medical device regulations, policies, and procedures administered by the Food and Drug Administration (FDA) and related industry standards and best practices. Mr. Ulatowski currently owns and operates Ulatowski Consulting, LLC in Fairfax, Virginia where he works as in independent consultant for industry clients regarding premarket submissions, post market surveillance activities, labeling, promotion and advertising, FDA compliance and quality system issues.

Mr. Ulatowski was awarded a Bachelor of Science degree in 1974, with a major in Microbiology from Pennsylvania State University. In 1987, he was awarded a Master of Science degree in Physiology/Emphasis in Biomedical Engineering from Georgetown University, School of Medicine, in a collaborative program with Catholic University, Department of Engineering. Mr. Ulatowski has additional college credits in computer science from the University of Maryland and Charles County Community College.

Mr. Ulatowski was an employee of the Food and Drug Administration (FDA) from November 1974 until January 2011. During his 36 plus years of employment with FDA he held increasingly responsible positions – first for 7 years in what is now known as the Center for Drug Evaluation and Research (CDER) and the remaining years in the Center for Devices and Radiological Health (CDRH).

From 1974 until 1978, he held the position of Microbiologist in the National Center for Antibiotic Analysis in CDER where he conducted laboratory analyses on antibiotics for regulatory certification purposes.

From 1978 until 1980, he held the position of Consumer Safety Officer (CSO) in the Office of New Drug Evaluation (ONDE) in CDER. While at ONDE he was a product manager for the Anti-inflammatory Drugs Group and he also contributed to the Oncology and Radiopharmaceutical Drugs Groups. He was the Executive Secretary for the Arthritis Advisory Committee and managed the flow of work and outputs concerning investigational new drug applications (INDs) and New Drug Applications (NDAs). He also was the division lead on major issues such as the Drug Efficacy Study Implementation (DESI) program and the Radiopharmaceutical Drug Research Committee program. In this capacity he became familiar with drug regulations, policies, and procedures as well as the related industry standards and best practices.

In 1980, he joined the Office of New Device Evaluation (NDE), Program Management Group, in the Bureau of Medical Devices (BMD) as a CSO. BMD was soon reorganized and joined with the Bureau of Radiological Health to form CDRH. NDE was renamed the Office of Device Evaluation (ODE).

In his first position in CDRH he was assigned to the Investigational Device Staff and was responsible for formulating policies and procedures to implement the new Investigational Device Exemptions regulation, 21 CFR Part 812, and other new human subject protection regulations dealing with informed consent and institutional review boards, 21 CFR Parts 50 and 56. he evaluated Investigational Device Exemption applications (IDEs) including

protocols for clinical studies. He also evaluated and quality controlled the IDE review work of all the divisions in ODE.

In 1988, he was promoted to the Director, IDE Staff. In that capacity he was responsible for managing and directing the IDE staff, for making final decisions on the sufficiency of IDE applications and the review of those submissions by FDA staff, and for IDE regulatory compliance in collaboration with the Office of Compliance, CDRH. In this position he was the CDRH expert on the IDE regulation, policies and procedures. He also became familiar with the industry standards and best practices related to the conduct of clinical studies on medical devices.

Later in 1988, he transferred to the position of Branch Chief, General Hospital Devices in ODE. As Branch Chief he managed and directed the branch staff, and was a primary reviewer of numerous IDE applications, Premarket Notification Submissions (510(k)s), Premarket Approval Applications, new product labeling, medical device reports (MDRs) and other types of regulatory submissions under the purview of his branch. The General Hospital Devices branch evaluated products classified by FDA under 21 CFR Part 880, General Hospital Devices. When he assumed this position until the end of his FDA career the government classified him as a Supervisory Biomedical Engineer. In this position he was an expert in premarket submission and medical device reporting regulations, policies and procedures as well as industry standards and best practices related to bringing a new device to the market.

In 1991, he was promoted to the position of Associate Director for General Devices in ODE. The scope of his responsibilities expanded to include the premarket evaluation of

surgical devices classified under 21 CFR Part 878 as well as the previously assigned general hospital products. In this capacity he had broader influence on guidance, policy and procedure development spanning the entire ODE. He formulated guidance, policies, and was directly involved in the review of many significant new products such as medical lasers and computerized medical systems. As an Associate Division Director, and earlier as a Branch Chief, he instructed ODE reviewers on the policies and procedures regarding premarket submissions. This training to staff included, for example, how to identify and assess predicates and reference device information contained in a 510(k), how to assess technological characteristics and performance data.

In 1996, he was promoted to the Director, Division of Dental, Infection Control and General Hospital Devices in ODE. In this position he assumed responsibility for more product areas and all the premarket regulatory activities associated with those product areas. During his tenure with FDA he reviewed and made agency decisions on thousands of 510(k)s and dozens of PMAs. During his tenure at FDA he also participated as a member on FDA committees, national and international standards committees, and the Global Harmonization Task Force (GHTF). The GHTF created guidance concerning industry standards and best practices related to the life cycle of medical devices and in vitro diagnostics. He was Co-Chair of the FDA committee that created the existing standards program in CDRH.

In 2003, he was promoted to Director, Office of Compliance, CDRH. As the Office of Compliance Director he was responsible for ensuring industry and human subject research compliance with the medical device, radiological health, and human subject protection laws and regulations administered by FDA. He was responsible for directing inspections of medical

device

manufacturing facilities and clinical research facilities, evaluating Quality System and MDR-related inspection reports and taking regulatory action based on those reports, classifying recall actions, creating risk management strategies, evaluating advertising, labeling and promotional literature, leading the FDA Device Field Committee, and directing responses to violations of import/export and registration laws and rules. In this position he was an expert in FDA law and regulations concerning medical devices as well as related industry standards and best practices.

He transitioned to the position of Senior Advisor for Enforcement in October 2010. In that position he led a team formulating strategies in advance of Congressional user fee reauthorization deliberations and provided expert advice to senior FDA leadership on premarket and compliance programs.

During his employment with the FDA, he received various awards from the FDA including the Distinguished Career Service Award, Award of Merit, Commendable Service Awards, and numerous other individual and group awards. He also attended and spoke at numerous professional meetings, courses and seminars.

Mr. Ulatowski issued a report on February 24, 2016, and issued supplemental reports on December 20, 2018 and June 19, 2019. In forming his opinions he relied on his 40 plus years of training, knowledge and utilization of the FDA medical device regulations, policies, review procedures and practices as well as his knowledge and application of related industry standards and best practices. The materials that he considered in forming his opinions are included within his reports.

Mr. Ulatowski will testify generally about FDA's mission, statutory, regulatory provisions and industry standards and best practices. He will testify about the FDA's medical device program and the life cycle of a medical device including classification and regulatory paths to market, the process for designing and testing medical devices prior to marking and risk management throughout the device's life cycle. He will testify about the FDA's requirements for post-market surveillance, and monitoring device experience including managing complaints, medical device reports and engaging in corrective and preventative actions. He will testify about applicable medical device labeling regulations including the required content of labeling, and the prohibition against false and misleading device labeling.

Mr. Ulatowski will testify about FDA's classification and approval of various Ethicon surgical mesh products and instruments including, Prolift Total. He will testify about the data and reports submitted to the FDA and the reasoning behind the FDA's clearance of surgical mesh and related products.

Mr. Ulatowski will testify about the "FDA public FDA Public Health Notification of October 20, 2008, Concerning Mesh for Pelvic Organ Prolapse and SUI" and its relevance to this case. Mr. Ulatowski will also testify regarding the FDA's reclassification of surgical mesh for Pelvic Organ Prolapse repair in 2016.

Mr. Ulatowski will opine that that PROLENE polypropylene material used in the Ethicon devices has demonstrated long-term safe and effective performance that supports its continued acceptance as an implantable material. He will testify that the FDA continues to reaffirm its confidence in the safety and effectiveness of PROLENE. He will also testify that

it was reasonable and proper and consistent with industry standards and practices for Ethicon to utilize PROLENE in various surgical products.

Mr. Ulatowski will testify that the FDA October 2008 Public Health Notice and 2013 updated FDA PHN for health care workers and patients on treatment of SUI support the argument that patient brochures were intended as only part of the interaction between the physician and patient regarding the potential treatment options and the warnings, precautions, and adverse effects for each option. He will further testify that it was reasonable and proper and consistent with industry standards to view the brochures as supplemental to physician interaction for purposes of informed consent.

Mr. Ulatowski will testify that the safety and effectiveness of laser cut mesh was properly verified according to regulations and that mechanically cut mesh continues to be reasonably safe and effective. He will further testify that Ethicon's addition of laser cut mesh was reasonable and proper and consistent with industry standards.

Mr. Ulatowski will testify that Ethicon was proactive in striving to ensure that its complaint and medical device reporting procedures, training of staff on those procedures, and implementation of those procedures were substantially compliant with regulations. The procedures and Ethicon's activities were also reasonable and proper and consistent industry standards and practices.

Mr. Ulatowski will testify that the adverse press and litigious environment that developed after 2011 FDA Safety Notice resulted in an atypical surge of surgical mesh related MDR reports.

5. Kellen Meade-Decker

Defendants' Designated Expert Witness – case in chief.

Live Testimony

Estimated Time of Testimony – 1 hour.

Substance of Testimony – *See* below

Ms. Meade-Decker is an employee of Johnson & Johnson whose testimony at trial would relate to financial and sales data concerning the product at issue and the Defendants' net worth. If the parties can reach a stipulation on these issues, Defendants will not call this witness at trial.

6. Mark Schneider

Defendants' Designated Expert Witness – case in chief.

Live Testimony

Estimated Time of Testimony – 1 hour.

Substance of Testimony – *See* below

Mr. Schneider is an employee of Johnson & Johnson whose testimony at trial would relate to financial and sales data concerning the product at issue and the Defendants' net worth. If the parties can reach a stipulation on these issues, Defendants will not call this witness at trial.

II. Fact/Lay Witnesses

1. Dr. Amanda Clark

Plaintiff's Treating Physician – cross-examination/case in chief.

Live Testimony

Estimated Time of Testimony – 1 hour.

Substance of Testimony – *See* below

Dr. Amanda Clark earned a B.S. in Chemical Engineering from Washington University in 1977, a Medical Degree from University of Louisville in 1981, and a Master of Clinical Research from Oregon Health & Science University in 2009. Dr. Clark completed a residency in Obstetrics and Gynecology from Oregon Health Sciences University in 1985 and a fellowship in Urogynecology from St. George's Hospital Medical School in 1989. Her fellowship was a focus on advanced surgical techniques dealing with pelvic floor disorders of incontinence, prolapse, and valve disorders. Dr. Clark is board certified in Obstetrics and Gynecology and Female Pelvic Medicine and Reconstructive Surgery. Dr. Clark was a urogynecology and menopause physician at Kaiser Permanente Northwest and retired in 2017.

Dr. Clark will testify about her professional experience as a urogynecologist, including her treatment of 200 to 300 patients for prolapse a year over her 27-year career. She will also testify that, throughout her career, she performed approximately 25 prolapse and 75 incontinence procedures a year using polypropylene mesh. Dr. Clark will testify regarding her professional experience with polypropylene mesh as part of her surgical practice. She will testify about the risk factors of mesh exposure, including smoking, and complications of mesh surgeries, the most common of which is urinary tract infections (UTI).

Dr. Clark will also testify that a bad outcome following surgery does not necessarily mean the mesh used is defective. Mesh exposure into the bladder also does not mean the mesh is defective. She will testify that polypropylene mesh continues to be used for prolapse repair. Dr. Clark has never encountered polypropylene mesh degradation over her career. Dr. Clark

will also testify regarding the risk factors of fistulas, including undergoing multiple surgeries and hysterectomies. Mesh is not a risk factor for fistula formation.

Plaintiff was treated by Dr. Clark at Kaiser Permanente in Oregon. Consistent with her deposition testimony, Dr. Clark will testify about the potential causes of abscesses, including diverticulitis. Mesh-associated abscesses are rare. Dr. Clark performed surgery on Plaintiff and found that Plaintiff's abscess was not related to her Prolift mesh. Therefore, Dr. Clark would not have performed the mesh excision had the cause of Plaintiff's abscess been established prior to the procedure. Dr. Clark will testify that she saw no abnormality or infection with Plaintiff's mesh in August 2012. Dr. Clark will also testify about Plaintiff's frequent UTIs and the difficulty of diagnosing UTIs in older women. She will also testify about menopause, atrophy, hypoestrogenic state, and how application of estrogen cream is used to heal small exposures.

Dr. Clark will testify that the balance of evidence and professional recommendations is to not remove mesh which is functioning normally and not causing a problem at the time. Dr. Clark will testify that Instructions for Use (IFUs) are not clinically useful documents and is not used regularly by clinicians. Dr. Clark relies on the medical literature for information regarding prolapse repair and surgical devices.

2. Dr. Michelle Ritter

Plaintiff's Treating Physician/Urologist – cross-examination/case in chief.

Live Testimony

Estimated Time of Testimony – 1 hour.

Substance of Testimony – *See* below

Dr. Michelle L. Ritter is a family medicine doctor at Kaiser Permanente in Portland, Oregon where she has practiced since September 2002. Dr. Ritter will testify that she first treated Ms. Smith as her primary care provider on October 31, 2002 and last saw Ms. Smith on January 8, 2021 (as of her deposition on April 23, 2021).

Dr. Ritter will testify that Ms. Smith's medical records indicate that she had an ovarian cyst removal, a bladder suspension, a full hysterectomy and surgical hernia repair prior to her first pelvic mesh surgery in April 2006.

Dr. Ritter will testify that Ms. Smith was diagnosed with fibromyalgia by a rheumatologist in approximately 2001 nearly a year before Dr. Ritter first treated her and prior to her first pelvic mesh surgery. Dr. Ritter will testify that Ms. Smith experienced fibromyalgia pain throughout her body – at times so severe she could not get out of bed – prior to April 2006. Dr. Ritter will also testify that Ms. Smith reported chronic lower back and/or abdominal pain prior to April 2006.

Dr. Ritter will testify that Ms. Smith was medically obese prior to April 2006 and that obesity is associated with increased risk of coronary artery disease and poor wound healing after surgery.

Dr. Ritter will testify that prior to April 2006 the medical records indicate that Ms. Smith was taking post-menopausal hormone replacement therapy and that Dr. Ritter reviewed with Ms. Smith the World Health Initiative which is a study that looks at the risks of chronic use of hormones after menopause (including heart attack, stroke and blood clots), but Ms. Smith did not enroll in the study.

Dr. Ritter will testify that Ms. Smith admitted to smoking a half pack of cigarettes a day since she was approximately 31 years old. Dr. Ritter will testify that she had multiple discussions with Ms. Smith about the dangers of smoking prior to April 2006. Dr. Ritter will testify that the reasons she recommends that patients like Ms. Smith stop smoking is because smokers are at risk of coronary artery disease, heart attack stroke, lung disease, obstructive pulmonary disease, peripheral vascular disease and other health issues. Dr. Ritter will also testify that smoking can interfere with healing following surgery. Dr. Ritter will testify that poor wound healing resulting from conditions such as smoking can lead to increased risk of mesh erosion.

Dr. Ritter will testify that Ms. Smith was diagnosed with psychological and emotional disorders including anxiety, depression, adjustment disorder, and major depressive disorder prior to April 2006. Dr. Ritter will further testify that Ms. Smith reported severe stress and anxiety for reasons unrelated to the mesh before April of 2006.

Dr. Ritter will testify that Ms. Smith was diagnosed with vaginal atrophy prior to April 2006. Dr. Ritter will testify that vaginal atrophy is something that can lead to pelvic pain unrelated to pelvic mesh.

Dr. Ritter will testify that Ms. Smith's medical records indicate that Ms. Smith was experiencing stress urinary incontinence symptoms for several years prior to April 2006. Dr. Ritter will also testify that Ms. Smith reported experiencing urge incontinence prior to April 2006.

Dr. Ritter will testify that Ms. Smith experienced symptoms of chronic urinary tract infections ("UTIs") and chronic cystitis prior to April 2006. Dr. Ritter will testify that

sometimes when Ms. Smith reported symptoms of UTIs her urinalysis was positive for signs of bacteria/infection and sometimes her urinalysis was negative. Dr. Ritter will testify that UTIs are common among women and especially post-menopausal women. Dr. Ritter will further testify that untreated UTIs can lead to chronic cystitis. Dr. Ritter will testify that chronic UTIs can cause kidney infection, kidney damage, chronic discomfort and pain, sepsis, and kidney failure. Chronic UTIs can cause mental confusion as well as agitation and depression.

Dr. Ritter will testify that Ms. Smith's medical records indicate that Ms. Smith "self-discontinued" prescribed medications, took unprescribed narcotics and discontinued medical treatment without the consent of medical professionals. Dr. Ritter will testify that the medical records indicate that a pessary was recommended to treat Ms. Smith's genital pressure, pain and urge incontinence. Dr. Ritter will testify that the medical records indicate that Ms. Smith tried pessaries twice but stopped using them both times – first because of discomfort and then because of bleeding.

Dr. Ritter will testify that Ms. Smith requested a surgical option to treat her genital pressure, pain and urge incontinence.

Dr. Ritter will testify that she is aware that Ms. Smith underwent vaginal mesh surgery, but Dr. Ritter did not make any diagnoses related to Ms. Smith's pelvic mesh. Dr. Ritter will testify that she does not recall personally observing visible mesh during examinations of Ms. Smith. Dr. Ritter will testify that she does not recall seeing change in Ms. Smith's symptoms after April 2006 and that she does not recall seeing a change in Ms. Smith's symptoms after the mesh was revised in July 2011. Dr. Ritter will further testify that to the best of her knowledge Ms. Smith is not still expressing concerns with UTI symptoms.

Dr. Ritter will testify that she never diagnosed Ms. Smith with any type of urinary dysfunction related to pelvic mesh.

3. Dr. Jeffrey Wheat

Plaintiff's Treating Physician/Urologist – cross-examination/case in chief.

Live Testimony

Estimated Time of Testimony – 3 hours.

Substance of Testimony – *See* below

Dr. Wheat graduated from UCLA Medical School. He is licensed to practice in Oregon and Washington. Plaintiff is his current patient. He has seen her in Washington. He completed his residency at University of Michigan Health System. He specializes in urology and has been board certified since 2013.

Dr. Wheat first saw Plaintiff in 2019 after she was seen by Dr. Matthew Forsyth in November 2019. He reviewed Dr. Forsyth's medical records and noted that Dr. Forsyth recorded a history of severe urinary incontinence, prior mesh exposure and mesh in the bladder revealed per cystoscopy. Dr. Forsyth attempted to remove the mesh in the bladder but unable to do so and, accordingly, Plaintiff was referred to Dr. Wheat.

Dr. Forsyth wrote a note to Dr. Wheat indicating that Plaintiff was a 75 year old patient with abrupt onset incontinence; that she had anterior repair in 2005 with vaginal mesh erosion; and that she showed two areas of eroded mesh proximal to the trigone. Dr. Forsyth tried to excise the mesh endoscopically but could not reach it due to a large cystocele which is a defect in the anterior wall of the vagina allowing the bladder to descend through the anterior wall of

the vagina down lower than it should be. Dr. Wheat is expected to testify that he does not believe the cystocele could be caused by mesh erosion.

Dr. Wheat saw Plaintiff on 11/29/19. She reported to him a history of vaginal mesh erosion with two prior excisions; persistent urinary tract infections; and eroded mesh on the anterior bladder neck. No fistula was identified. Plaintiff also reported continued incontinence which Dr. Wheat did not know if it that was caused by mesh erosion at that time. His physical exam noted that Plaintiff's vagina was atrophic. Plaintiff did not complain of vaginal pain. There was no exposed mesh in the urethra but he did identify mesh with calcifications in her bladder. Nonetheless, Dr. Wheat did not testify that her urine leakage was necessarily coming from her bladder. He saw mesh eroding into her bladder which is something he has seen with other patients with pelvic mesh.

Dr. Wheat developed a treatment plan which was complicated by her cystocele. The plan was to dilate a suprapubic tract and then use a flexible cryoscope and laser to treat the mesh without any need for retroflection. He explained to her that any surgical procedure has a risk of pain. Age is also associated with increased risk of surgical procedures.

He further planned to use a laser to treat the calcifications and stone and then use the laser to treat or ablate, destroy any exposed fibers of mesh to try to get that underneath the bladder urothelium. The desired result was that there would then be a layer of urothelium that could heal over the top of any mesh and seal it off. He went over risks with her including bleeding, infection, fistula formation, and bladder damage.

On January 3, 2020, he performed the procedure he had discussed with Plaintiff. He noted that there was no active fistula at the time of that procedure. He noted there were two

areas of mesh erosion into her bladder, one directly behind the trigone and one about 5 mm above this. He was able to remove all the mesh through the urothelium. There was retained mesh under the urothelium. There was no perforation of the bladder. This is what he would expect for a mesh erosion. As to the retained mesh under the urothelium, his goal with this procedure was never to remove all her mesh. His goal was to remove the mesh in the bladder above the urothelium then allow catheter drainage to allow that skin layer to heal over the mesh sealing it under the skin layer.

On June 24, 2020, he performed a second procedure to attempt repair of a vesicovaginal fistula secondary to mesh erosion into the bladder. His note indicates successful closure of the vesicovaginal fistula. That means that his impression at the time was that there was no urine coming through at the end of the procedure and he deemed it a success.

He also noted that the urothelium and vaginal epithelium was extremely thin. Given this, extensive dissection was not undertaken and no additional mesh was excised. His goal was to excise enough mesh to get it away from the site of the fistula so that he could provide a multilayer repair and prevent the fistula from occurring. His goal never was to remove all the mesh.

On follow-up on April 22, 2021, Plaintiff reported continued urinary incontinence, but on cystoscopy, Dr. Wheat was not able to document leakage from the fistula repair site.

Dr. Wheat will testify that he conducted a urodynamics study that showed her bladder did not squeeze normally. This is a common finding in an elderly woman. She voids by using the Valsalva pressure. She pushes and urine comes out. He recommended intermittent

catheterization so that she could empty her bladder without using additional Valsalva pressure to empty her bladder.

He has not seen Prolift mesh erosion into the bladder cause life threatening complications kidney failure, or mental confusion.

Dr. Wheat is not qualified to perform the procedure of implanting a Prolift mesh. He would reserve judgment on if he would recommend Prolift mesh to a patient. He doesn't treat prolapse. So he can't comment on if that was the preferred surgical method of treating prolapse at the time. Use of the TVT was within the standard of care to treat her SUI.

He never told Plaintiff that any of the mesh implanted in her was defective. He never told her that a defect in the mesh implanted in her had caused any of her problems. He never formed the opinion that any of the mesh implanted in plaintiff was defective. He knows Dr. Zenthoefer. He has not talked to him about plaintiff's care and treatment. He is aware that Dr. Zenthoefer was the implanting doctor in April 2006. He reviewed Dr. Zenthoefer's operative report. He also reviewed his pre/postoperative progress notes. At the time that Dr. Zenthoefer implanted the pelvic mesh device, that was the standard of care.

Dr. Wheat would expect that Dr. Zenthoefer discussed the risks and benefits of implanting mesh before the procedure. They go through a description of the procedure with every patient. Dr. Zenthoefer says he discussed risks including death, heart attack, stroke, blood clots, infections, surgery can fail, or it may not work in the short or long term. Those were known risks of mesh surgery back in 2006. Dr. Zenthoefer talks about drug reactions, allergic reactions, infections, and vaginal mesh erosion – which is probably the most common one. Dr. Zenthoefer's definition of vaginal mesh erosion being the mesh coming through the

vaginal skin coming out the vagina is consistent with his definition. Vaginal mesh erosion including the mesh internally eroding into other structures, organs and things, was a known risk at the time. Mesh being able to erode into the rectum and abdominal organs were also known risks in 2006. Dr. Zenthoefer says he discussed those risks with plaintiff.

Dr. Zenthoefer also discussed with her dyspareunia, pelvic pain, need for further surgeries, nerve injuries, bowel, bladder, rectal injuries. Based on his review of Dr. Zenthoefer's testimony, all of the conditions which plaintiff experienced and for which he treated her were included within Dr. Zenthoefer's discussion of potential risks. Dr. Zenthoefer talked to plaintiff about mesh erosion. Plaintiff did not experience any complications that were not known risks of mesh surgery in 2006. Based on Dr. Zenthoefer's testimony, Plaintiff did not experience any complications that were not identified by Dr. Zenthoefer as a risk of the mesh procedure.

He is aware that Prolift mesh uses polypropylene. He is aware that polypropylene is used in meshes that continue to be used today for treatment of SUI. He uses it in his practice for SUI.

That continues to be within the standard of care. By and large, his patients have tolerated the use of polypropylene mesh in surgical treatment. Overall, his patients have benefited from the use of polypropylene mesh in surgical treatment of their incontinence.

He is aware that plaintiff is an every day smoker. Nicotine is a vasoconstrictor. They rely on a patient's blood flow to improve wound healing. Anytime an incision is made, there is an impairment in wound healing in people using vasoconstrictors like nicotine. He would assume that chronic smoking increases the risk of developing mesh erosion and fistula

formation because smoking impairs wound healing. Vaginal atrophy also increases the risk of mesh erosion and fistula formation.

Fistula formation is a risk of many pelvic floor surgeries, including prolapse surgeries that don't use mesh. All pelvic floor surgeries have risks of neuromuscular problems, the need for repeated surgeries, recurrence or failure, foreign body response to sutures, non-mesh grafts or other foreign grafts; exposure or extrusion of sutures or grafts.

Any foreign body implanted into a patient can result in a foreign body reaction. Foreign body reactions can be asymptomatic or symptomatic with pain or scarring. The fact that there is a foreign body reaction does not necessarily mean the patient is going to have pain or untoward consequences. All of these risks can be acute or chronic in general. Fistula formation from non-mesh pelvic floor surgeries can develop soon after surgery or sometimes delayed years later.

These risks can be mild or severe complications. Vaginal mesh erosions can result in mild discomfort or inconvenience to the patient. He has seen some patients with mesh erosion that weren't even aware they had erosion.

A bad outcome with surgery does not mean that there was something wrong with the surgery itself. It doesn't mean there was something wrong with the product used during that surgery. During a mesh surgery to correct prolapse, the fact that there was a bad outcome doesn't mean there was something wrong with the product. Patient factors can affect whether a patient is more likely to have a bad outcome or complication. One of those factors for pelvic floor surgery and incontinence surgery would be vaginal atrophy. Another factor would

the effect of aging itself. Plaintiff was 78 years old when he began treating her. Incontinence in a 78 year old woman is a common problem.

Plaintiff's medical history includes three prior pregnancies with vaginal deliveries. Her largest baby was 9 lbs. and they used forceps. She has a history of reporting that she felt like her insiders were falling out and of incontinence. She had a total hysterectomy with removal of ovaries and uterus. Her prolapse surgery required both anterior and posterior repair.

At least as far back as 2006, she was having to push her bladder down into her vagina as well as her rectum push down into her vagina. It was recommended that she try two conservative methods to treat her prolapse, Kegel exercises and pessaries, before surgery but she reported that she wasn't doing the exercises and that the pessaries didn't work for her either.

Before her Prolift surgery, she reported having to work at being able to have urinary voiding by leaning to the left or right. She also admitted to always splinting with bowel movements. Usually, that is in reference to a posterior prolapse or rectocele. The rectum descends into the vagina and if you Valsalva and have a bowel movement, it pushes in the wrong way. If you insert a finger into the vagina, you can push the rectum more in a straight line and aid in having a bowel movement. So this means that before Plaintiff had any pelvic mesh, in order to have a bowel movement, she had to insert her fingers into her vagina.

She has a reported history of a 7 hour hysterectomy during which she was diagnosed with severe adhesive disease characterized by the doctor as having a bucket of glue in her abdomen. Adhesions are connections between organs inside the abdomen. Normally the

intestines and omentum are able to move freely inside your abdomen. In any setting of inflammation, either surgical or peritonitis, you can develop adhesions where those organs stick together making surgery very difficult. Adhesions can cause pain.

Fistulas can be a risk of surgery used to address adhesions. Fistulas can be a risk of hysterectomy. Certain bladder surgeries can cause fistulas. Hysterectomies and bladder repairs can compromise the integrity of organs so that you become more susceptible to development of fistulas later.

One year after Plaintiff's mesh implant in April 2006, there had been no mesh erosion. On exam by Dr. Zenthoefer on January 25, 2011, Plaintiff was positive for trabeculations. In patients with outlet obstruction of urine flow blockage, they can develop enlargement of the muscle. The enlargement of the muscle fibers usually correlates with outlet obstruction. You can't tell from this if that relates to the mesh. He sees that in women both with and without mesh. It can be symptomatic of chronic overdistention, incomplete emptying of the bladder. With a woman of plaintiff's age, that would not be an uncommon condition. She was also positive for bladder diverticula. When you get those trabeculations, you can get weak spots between those muscle fibers. The bladder urothelium or skin can have less muscular wall backing behind it because the muscle fibers become like bands. The bladder skin will kind of pooch out between those bands of fibers. That is a condition that is not uncommon in women of plaintiff's age even without mesh. It would make him concerned for an outlet obstruction that would probably increase her risk of bladder erosion.

On July 3, 2012, at a visit with Dr. Clark a small part of vaginal mesh exposure was found on exam which was excised. There was no bladder erosion six years after implant. Dr.

Clark found adhesions and performed a lysis of those. The note states there are adhesions between the bowel and vaginal cuff. The small bowel was also adhesed to the cecum or small bowel. There was an abscess found with some infection. There is no way to tell if the mesh caused that infection. Dr. Clark also noted that Plaintiff's vagina was quite short. He cannot attribute that to the Prolift mesh. There was no fistula noted and no injury to the bladder.

Looking again at the office visit from 10/1/19 from Dr. Forsyth. This is 13 years after the mesh implant. Plaintiff was 78 years old at the time. The note indicates she had mesh erosion, recurrent UTIs, abrupt onset urinary incontinence and constant leaking with no SUI. A cystoscopy was performed. Her urethra was normal. There were two areas of eroded mesh within the bladder which are the areas he addressed surgically. Thirteen years after the implant is the first evidence of erosion into the bladder. No fistulas were identified.

When he performed his procedure on January 3, 2020, he did not find an active fistula. He advised her to quit smoking to improve wound healing and reduce the risk of fistula formation. She did not initially quit smoking when he advised her. He did not notice in reviewing her records that prior doctors advised her to quit smoking.

The catheter was removed on 1/30/20 and no fistula was seen at that time.

He did a cystoscopy on 3/4/20. He noted that the more superior exposed mesh had completely epithelialized. That means that his plan to laser the mesh under the skin of the bladder at that point had worked and skin had grown over it. His note says the inferior or caudad lesion was completely covered with urothelium and skin layer of the bladder. Both lesions had actually been covered with skin which was his goal. That was what he was hoping for. There was no exposed mesh that could be visualized at that time. Once he filled the

bladder with water, he saw water coming through vaginally which is when he identified the vesicovaginal fistula. Under pressure, he saw leaking from that connection. This was the first time a fistula was identified for her. This was 17 years after her mesh surgery. And she had undergone a number of cystoscopies or cystourethroscopies prior to this. Until 2019, there was no erosion in the bladder noted. Dr. Forsyth was the first to see the bladder erosion.

Aging is an independent risk factor for mesh erosion. He never formed an opinion as to the mechanical cause of her mesh erosion. He never formed an opinion about the fundamental cause of her mesh erosion. The cause of her fistula was a result of the erosion itself.

Given that there was no fistula seen before his cystoscopic procedure and that there was a fistula formed after, he would say that there likely was a relation in his treatment of the vaginal mesh erosion and her thin tissue that resulted in a fistula. He wouldn't have been able to assess if there was mesh degradation. He saw no evidence of mesh curling. He didn't have an opportunity to evaluated mesh shrinkage or contraction. He saw no evidence of fraying, necrosis or mesh infection.

He did see a foreign body response. That was the calcification, the stones and the edema around the area of the mesh erosion. That was consistent with the known risk of mesh surgery back in 2006.

Mesh exposure is multifactorial. Plaintiff had a history of vaginal atrophy and she was postmenopausal. He was aware that she had been advised to use hormone supplements. If she had not been using hormone treatment as directed, that would have increased the risk of her developing vaginal atrophy. That could lead to an increased risk of mesh erosion. Menopause

or the lack of estrogen leads to decreased vascularity of the vagina which will impair wound healing. The fact that she had cystocele is evidence of laxity or weakness of the bladder tissue.

Compromised or poor blood circulation can increase the risk of developing mesh exposure or fistula. Obesity, infection, prior surgeries, and aging can increase the risk of mesh exposure and fistula formation.

Based on Dr. Zenthoefer's testimony regarding her medical history, including the adhesive disease, he would say an abdominal approach to repair her prolapse would be a very bad idea.

If he were to attempt to repair her fistula, it would require her to obtain catheter drainage for the rest of her life. If she elects to stay the way she is and leak through her fistula, she would have less drainage if she used a catheter. Another option is to not use a catheter and accept the drainage.

He knew before he performed that surgery that development of a fistula was a potential complication. The surgeries performed in 2006 and then the subsequent mesh erosions performed after that all carried with them a risk of development of a fistula. He cannot say that plaintiff experienced any complications a result of a defect in the mesh.

Plaintiff must now self-catheterize in order to urinate. He cannot say that the need for catheterization is a result of the Ethicon mesh because that is a common finding among women with and without mesh.

He does not recommend Plaintiff undergo a cystectomy. Alternative procedures include placement of a suprapubic catheter.

Plaintiff's past and continued smoking and failure to apply vaginal estrogen cream, contrary to the advice of her doctors, caused or contributed to the development of her vaginal erosion/exposure, and prevented a simple correction of the erosion/exposure which led to the development of further erosion/exposure and fistula.

4. Dr. Peter Zenthoefer

Plaintiff's Treating Physician – cross-examination/case in chief.

Live Testimony

Estimated Time of Testimony – 3 hours.

Substance of Testimony – *See* below

Dr. Zenthoefer graduated from Oregon State University in 1976. He attended Oregon Health Sciences School of Medicine from 1976 to 1980. He did his Residency in Obstetrics/Gynecology from 1980 to 1984. He completed a service obligation at Fairchild Air Force Base in Washington from 1984 to 1987 and then began a clinical career. He retired in September 2015. Most of his career was in Oregon. He also held licenses in California and Washington at different times. He board certified in Ob/Gyn until 2016 after his retirement. Before his retirement, he was affiliated with a urogynecology training program at Oregon Health Sciences Center teaching fellows as they rotated through Kaiser Medical Center.

He cannot estimate how many patients he saw during his career for pelvic organ prolapse ("POP"). It's a very common problem. In 2009, pretty much all of his practice, more than 95%, were POP patients. In 2005/2006, during the day he was primarily in urogynecology treating POP patients.

Prolift was one of the products he used to treat POP. He's not sure how many times he used it prior to 2006. They were using it quite a bit in 2005. By 2006, it was a product with which he was comfortable and familiar. He was trained on non-mesh surgery to treat POP. They did anterior colporrhaphies, posterior colporrhaphies, colpocleisis, abdominal sacral colpo-suspensions, sacrospinous suspensions. 2005 was not the first time he used mesh to treat POP. For a number of years prior to that, they were using mesh abdominally to treat POP. They were doing abdominal sacral colpo-suspensions using different kinds of mesh products.

They used a piece of mesh that they custom-tailored and cut to fit the patient. He thinks they used a different product before using Ethicon's Prolift kit for a short time but primarily, after doing a review of the different products on the market, their group decided to use the Prolift. They thought it was one of the best products on the market. One of the main reasons for using Prolift was that it gave them an option that was much more patient friendly.

Prior to Prolift, they would make a big incision in the abdomen and patients would have this really big surgery and long hospital stay. There was morbidity and complications. A lot of their patients are older and some just bare squeaked by. Prolift was much smaller. The Prolift surgeries were much more patient friendly. There was less pain, less morbidity, and shorter hospital stays. They promised to give the same long-lasting results. After several years experience with Prolift, they saw the results were overall pretty good but not quite as good as they hoped. Every surgery has complications. The complication rate with Prolift was maybe a little higher. Then they learned how to do laparoscopic sacral colpo-suspensions which they felt was a better way to go. They started doing the laparoscopic procedures somewhere in 2007-2009.

He attended Ethicon professional education events before they started using the Prolift. They went to an Ethicon surgical training conference. The Ethicon training for Prolift was very helpful, very well done. He agrees that Ethicon's education event provided him with information on how to perform the procedure but it didn't teach him how to be a pelvic floor surgeon. They were all pelvic floor surgeons. This gave them additional information.

He first saw Plaintiff on 1/30/06. Plaintiff was 64 years old. Plaintiff said it felt like her insides were falling out. She also had some complaints of mild SUI. He did a physical exam. She was also complaining of difficulty starting her urine stream. She would have to change position, leaning to right or left, to get her stream to start and empty her bladder. She had difficulty eliminating or passing bowel movements. She had to insert her fingers either inside her vagina or push on the perineal body and help express stool. She was incontinent of flatus. On exam, he noted that the perineal body was somewhat attenuated.

It looked like it had been damaged in childbirth. Her largest baby was 9 pounds with forceps delivery which often causes damage to the pelvic floor. She had a large cystocele – the upper vaginal wall and bladder were falling down. She had a moderately large rectocele. The vaginal cuff was well supported while she was lying down. She had a hysterectomy – so no cervix, uterus or ovaries anymore.

Her bladder was dropping down. When that happens, the urethra kinks and patients don't leak much urine. They pushed the bladder up and had her cough and they were able to demonstrate some urine leaking with coughing. That's SUI. He did a cystoscopy which was normal in the bladder. The urethra was closed nicely and functioning well. Plaintiff told him

that when she had her hysterectomy that her doctor said it was like her abdomen was filled with a bucket of glue from severe adhesive disease. Adhesions are scar tissue. Severe adhesions are when everything is scarred together. That is when there is dense scar tissue between loops of bowel, bowel and bladder, small bowel and rectum, the ureters and peritoneal lining.

It's interesting that she reported that her hysterectomy took 7 hours. That is an incredibly long time. Normally it should take 1 ½ to 2 ½ hours. That is an indication that she had severe adhesive disease. When you have that kind of information, it tells you that you should not do surgery in this patient's abdomen, that it is incredibly risky and only in a life and death situation should you enter that person's abdomen.

His conclusion was that in no way would he want to make an incision in her abdomen. So she was the ideal candidate for vaginal repair and Prolift. He probably didn't discuss Prolift very much with her at that point. At the first visit, he tries to avoid talking about surgery and tries to talk about nonsurgical treatments. Those would include PT. His plan was a PT referral. When the tissues in the pelvic floor and vaginal area become stronger, they improve in their functional ability with estrogen hormone cream. He recommended that.

Sometimes incontinence is provoked by dietary factors. He recommended some diet modification – cutting out caffeine and soda. He would ordinarily recommend pessaries for prolapse. She had seen Dr. Miksovsky, another Ob/Gyn, and his notes say that he treated her with 2 pessaries and both were unacceptable to the patient. The first was painful and the second caused bleeding. So she stopped using the pessaries. He doesn't think she was willing to try a pessary again. Otherwise, he would have done that. In January 2006, because of the POP,

she described it feeling like her insides were falling out. She couldn't pee normally or eliminate stools.

She was incontinent of flatus and urine. It was affecting her life quite a bit. Looking at record from 4/6/06. On March 14th, plaintiff had called his office and told them that she did not want to do PT or conservative therapy and that she wanted an appointment with him to discuss surgery. His nurse had tried to convince plaintiff to try the PT because his nurse was a really big proponent of conservative therapies.

Plaintiff didn't want that. So she came in on April 6th to discuss it with him. Plaintiff was done with conservative therapy. They discussed doing an anterior and a posterior colporrhaphy with Prolift. They discussed doing a midurethral sling. It was his preference to do a TVT sling because it enters the abdominal cavity and she had the history of severe adhesions. They decided to do the transobturator sling which avoid going into the abdomen. He didn't consider using native tissues because his understanding is that native tissues were not helpful and not associated with improved result. He doesn't think they discussed that. He thinks they discussed doing just an anteroposterior repair.

He recommended the Prolift because it was associated with better long term results. He had been doing anteroposterior repairs since his residency in the 1980s and they just have a very high failure rate. When you use the patient's own tissue, they have very high failure rates. Using mesh is associated with better long term results. Prolift was a reasonable and appropriate option for plaintiff. In his hands, Prolift worked to treat his patients with prolapse.

Looking at the informed consent signed by plaintiff on 4/12/06. It says a PARQ discussion held. PARQ stands for procedure alternatives risk questions discussed. He spent a lot of time talking about risks to patients because he thinks surgery is a big deal. You start out with the obvious ones – there is a small chance you could die. There could be major morbidity. You could have heart attack, stroke, blood clots, infections. The surgery can fail. There is no guarantee the surgery will correct the POP. There is no guarantee it will work in the short or long term.

There are medical complications – drug reactions, allergic reactions, infections – where the surgery is done or in other parts of the body, like lungs, bladder, kidneys. There are all the risks and complications of a surgery where they don't use mesh. Then, when they do use mesh, there is a whole other discussion they go into. The most common complication with mesh is vaginal mesh erosion. He would have told her that vaginal mesh erosion is mesh coming through the vaginal skin, coming out the vagina. He is sure he discussed complications associated with vaginal mesh erosion with her.

He would have also mentioned that mesh can erode into other structures, organs and things. But specifically vaginal mesh erosion. The most common thing the patient would notice would be vaginal bleeding, spotting and discharge. If they were sexually active, their partner might notice it because they feel it during intercourse. It feels like sandpaper. They got poked. He discussed those things with everybody. He also discussed the possibility of having a second surgery to deal with the mesh erosion. The mesh can erode into the rectum or other abdominal organs. It was all discussed. Any kind of pelvic surgery can be associated with pain. That was discussed.

As for doing the sling under bladder, he had a standard discussion in which he told patients that tensioning the sling was very tricky and critical. If they didn't tension the sling tight, their SUI wouldn't be better. If they made it too tight, they would have trouble emptying their bladder. He would also discuss risks of dyspareunia, pelvic pain, different kinds of morbidity, need for further surgeries, nerve injuries, bowel injuries, bladder, rectal injuries. He schedules 30 minutes for a pre-op appointment.

However, he usually went over to 45 minutes to have this discussion. Most of that is going over the consent form. After having that discussion, plaintiff decided to proceed with the surgery.

He performed surgery on 4/17/06. He does not recall any complications during the procedure. It went very well. He did it with his partner, Audrey Curtis, who is a very skilled surgeon and they worked well together. Standard discharge instructions following Prolift procedure would be obvious ones like restrictions in lifting.

Don't lift more than 10 lbs. for the first couple of weeks and no more than 15 for the next month. They told the patients not to put anything in the vagina – no intercourse, douching, vaginal estrogens. They had discussions about urinary retention, voiding problems, bladder infections – all common issues after surgery.

His next visit with Plaintiff was 4/25/06. When she was discharged from the hospital, she had a little leg pain but that was now completely resolved. She was voiding normally. She no longer had SUI. She was taking tub baths. She had no concerns. The incisions were healing well. He inserted a very small speculum into the vagina and very carefully examined her. All the incisions inside were healing. He could not see any mesh. He thought she was

doing very well. He encouraged her to start using estrogen cream when she was more comfortable.

He saw her again on 5/31/06. She was doing very well. She was very pleased. She no longer had to splint for bowel movements. She had no SUI or urgency symptoms. She was complaining of a little cloudy urine and a little burning and she wondered if she had a bladder infection.

He started her on the Premarin cream. That was his routine. The tissues in the pelvic floor in the vaginal area are different from tissues elsewhere in the body. They are estrogen dependent. They need estrogen to be healthy and strong. Without estrogen, especially when someone is 65, they atrophy and become thin and weak. The incidence and likelihood of mesh erosion increases quite a bit. So for all of his patients who had pelvic floor reconstruction surgery, he recommended vaginal estrogen. The local effects were very important. The amount of systemic absorption was small and unlike oral estrogen, this is very, very safe.

He saw Plaintiff on 8/23/06. She was very pleased with the results of the surgery. The problems with her bowels were completely resolved. Looking at a visit from 7/18/07. No urinary incontinence during the day.

She had a little leakage at night. Her pad was a little wet. She had to get up 3x a night. That's pretty common when people are in their 60s. She is able to walk to the bathroom without leaking but when she arises from the supine position, she leaks a little bit. That's not too unusual. She complained of frequent UTIs. The last one was in December. This note was done in July. She said she takes cranberry juice when she feels she has symptoms. She had a urethral discharge that was slight green in color.

She said she was using estrogen cream. She was rarely sexually active. Her husband was pretty ill. She told him the surgery had helped her with 90% and she no longer leaked urine with activities in the daytime. She said she had a little bloody discharge from the urethra. He did measurements on this day. Her bladder was fairly well supported. The posterior vaginal wall was fairly well supported. It looked like the surgery was successful.

Looking at his visit with Plaintiff from 4/5/11. She reported some urgency symptoms like when she had a UTI in the past. That was her only concern that day. His note says he spent 25 minutes with her with more than 50% discussing mesh erosion, vaginal atrophy and urgency symptoms. He did an exam. At the apex of the vagina, there was about a 1 cm area of exposed mesh. There was no abnormal induration or purulent discharge. No sign of infection. He did a rectal exam. No mesh in the rectum. So they had a long discussion about the mesh in the vagina. The other thing he noticed on exam was that her tissues were very atrophic.

They were very thin, fragile and weak. That was something he referred to earlier that could lead to mesh erosion. They spent a lot of time talking about the importance of using vaginal estrogen. Looking at visit from 6/24/11. He first noted the little bit of mesh erosion in January. Sometimes that heals over in patients. The vaginal skin will grow over the mesh and you get re-epithelialization. He saw her in June to see if that had happened and she was using the estrogen cream. It does not appear that she had any complaints.

His note does not mention that she was having pain. He would have put that in his note if she had pain. Generally, mesh erosion is not associated with pain. The patients are generally

unaware of that. They may notice a little funny vaginal discharge. Most typically, their partner notices it during intercourse. But she was not sexually active. The plan they made in January was to remove the part of the mesh that was eroded if using conservative therapy first didn't work – 6 months of vaginal estrogen cream to allow it to heal. The surgery would be to remove the mesh, sew the vaginal skin edges together and give it a chance to heal.

Ultimately, she required surgery to remove the piece of exposed mesh. He discussed the risks of this surgery. This was a much shorter surgery but risks are still there. The location of the mesh exposure was very close to the bladder, rectum, pelvic nerves, ureters. All of those things could be injured. He always did a cystoscopy to make sure the bladder was functioning. Patients are always told there is no guarantee that this is going to heal okay. He thinks he told patients there was maybe an 80% chance this would heal and 20% chance they would have a mesh erosion again in the future. He always emphasized the importance of using estrogen in the vagina.

He thinks he read at one of the later notes that she wasn't actually putting estrogen in the vagina. She was just putting it on the outside. So even though his note says she was using estrogen daily, later on, in retrospect, he figured out that she really wasn't using it at all up at the top of the vagina, she was just using it on the outside which didn't really help where the mesh was exposed. Her failure to use the estrogen in the way that he had recommended could have absolutely contributed to the mesh erosion.

After the mesh removal, she returned to see his nurse for a voiding trial. The note indicates that she may have gone home from the surgery with a Foley catheter because she couldn't pee. She was now in the office to see if there was resolution of the swelling and she

could pee. His nurse discovered that she voided normally. The catheter was removed and she went home.

No surgery is 100% risk free. He familiarized himself with the safety information about mesh before using it for the first time. He educated himself as a member of professional societies, AUGS and IUGA. He read publications regularly and attended continuing education conference.

He frequently discussed things with his colleagues. All pelvic floor surgeries have basic known risks. A bad outcome does not mean there was something wrong with the surgery. A bad outcome does not necessarily mean there was something wrong with the product. If plaintiff experienced erosion, that does not mean that there was something wrong either with the surgery or with the product. He wants to add that her noncompliance, her failure to use estrogen inside and at the top of the vagina, at the vaginal apex, a common area of mesh erosion, was a contributing factor.

He thinks the benefits of Prolift for his patients outweighed the risks of Prolift. That was true during the entire time he used Prolift in his patients. He found that Prolift was safe and effective treatment in his patients. Again – no surgery is guaranteed safe. That was something he knew before he implanted the first Prolift product into one of his patients. They had some brochures in their clinic that talked in general terms about POP and treatment for that.

Prior to the time that he implanted Prolift in plaintiff in 2006, he was aware of the risks that mesh material may become exposed; and exposure may require treatment. Prior to

implanting Prolift in plaintiff in 2006, he was aware that some of the complications associated with pelvic surgery involving mesh included injury to blood vessels of the pelvis; difficulty urinating; pain; scarring; pain with intercourse; bladder and bowel injury. He discussed those risks with plaintiff.

There are also risks associations with non-mesh POP surgery including acute and/or chronic pain with intercourse; acute and/or chronic pain; vaginal scarring; infection; urinary problems; organ and nerve damage; bleeding; wound complications; inflammation; fistula formation; neuromuscular problems; repeated surgeries; recurrence or failure; foreign body response; erosion or exposure or extrusion of sutures or grafts; and contraction or shrinkage of tissues.

He was aware of all these potential risks of non-mesh surgery before he implanted Prolift in plaintiff. He was aware that any one of these complications could be temporary or chronic in nature. He was aware that some of these could be mild, moderate or severe. Showing him a list – he was aware of all of those risks associated with mesh repair for POP. He was aware of them before implanting plaintiff. That is information he took into account when going his risk-benefit analysis with respect to plaintiff.

He had no evidence that plaintiff had been harmed by a foreign body reaction after Prolift implantation. The mesh exposure at the top of the vagina seemed to be pretty asymptomatic. He is the one who noticed it on a routine exam. He saw no evidence that plaintiff experienced any cytotoxicity.

There was no evidence that plaintiff's mesh degraded, that she had roping or curling of the mesh; or that there was any evidence of infection with the mesh. There was no purulent drainage or pus. No induration. No hallmark signs of infection.

Dr. Zenthoefer will testify that while POP generally is not a life threatening disease, it can be very distressing to the patient. It can be limiting in terms of their ability to engage in social activities and leave the home. In very rare cases, it can be life threatening.

Plaintiff would never have been a candidate for laparoscopic surgery because of all the adhesions. It would be even more dangerous than making an open incision, much more dangerous. When somebody has lots of adhesions, they favor a laparotomy approach where they make a big incision over a laparoscopic approach.

The pathology report for the mesh that he excised said the mesh cause an inflammatory reaction in her vagina and that there was a foreign body giant reaction. Whenever there is an injury or foreign body there is always an inflammatory reaction. That's very, very common in pathology reports. That just means that there was a synthetic material and this was how her body was handling this. It's the body's reaction to a permanent implant like Prolift. It's more common when you put mesh in somebody. He knew that was a risk in 2006.

He is aware that the FDA at that time recommended that any surgeon considering transvaginal mesh to treat POP inform patients that the mesh is permanent and that some complications associated with the implanted mesh may require additional surgery. In his practice, they always really tried to encourage patients to try nonsurgical things first. So with plaintiff, they tried pessaries, PT and hormone therapy. She was the one who didn't want to

try another pessary and didn't want to do PT. His clinic had more pessaries than probably any other to try to fit patients and his nurses were big proponents of that.

There was no incentive for him to do unnecessary surgery. He got paid the same. It was Plaintiff who was really pushing for surgery. His staff would have gladly treated her longer non-surgically. The implantation of transvaginal mesh was not the only surgical option available at that time.

At that time he implanted Plaintiff's Prolift, it was his understanding that Prolift had been approved by the FDA for treatment of POP. Someone from Ethicon told him it was FDA approved. It would surprise him to learn that that's not true. He was not aware that it was not FDA approved until 2008. In 2006, he quite possibly still would have implanted a non-FDA approved medical implant in plaintiff. In medicine, there are lots of things that are done that are not FDA approved, like Terbutaline to stop labor. There's a big expensive process to get something FDA approved and if there is a large body of medical evidence suggesting that something is safe and effective and it's in common use, that can be the standard of care.

When he was talking about how he would customize and cut his own mesh for use before Prolift, they would use Gynemesh, the exact same mesh that was used in Prolift, TVTs and TOTs. His experience with Gynemesh entered into his risk benefit analysis when deciding to use the Prolift in plaintiff. They had a lot of history and experience with Gynemesh. That was a big improvement over the meshes they used before that.

Plaintiff was noncompliant. She didn't use the estrogen vaginally. That's a big factor. He think that's a big reason why she had so many problems. The other issue is that she was a smoker and smokers have many more problems. Their risk of mesh exposure is greater.

The estrogen was prescribed after her first surgery. They prescribe that for everybody after pelvic reconstructive surgery, with and without mesh. This was something that his group felt was very important. There were lots of evidence in the literature that showed that the connective tissue stayed stronger in women longer who used estrogen and it quickly became weaker if they failed to use the vaginal estrogen. They perhaps increased the frequency of use after surgery. And if somebody had mesh erosion, they might recommend it daily.

5. Axel Arnaud

Defendants' Fact Witness – Scientific Director for Ethicon Gynecare Europe

Videotaped Testimony

Estimated Time of Testimony – 1 hour.

Substance of Testimony – *See* below

Defendants will present Dr. Axel Arnaud through his designated deposition testimony, which was previously disclosed to Plaintiff in this action. Dr. Arnaud was the Scientific Director for Ethicon Gynecare Europe at the time of the Prolift's launch. Dr. Arnaud will testify regarding certain facts and circumstances surrounding the development and launch of the Prolift, the pre-launch data and testing available to support the launch of the Prolift, as well as the safety and effectiveness of the Prolift in general.

Dr. Axel Arnaud was the Scientific Director for Ethicon Gynecare Europe at the time Ethicon launched the TVT (1998) and TVT-O (2004). Dr. Arnaud will testify regarding certain facts and circumstances surrounding the launch of these products, the pre-launch data and testing available to support the launch of these products, as well as the safety and effectiveness of these products in general.

Dr. Axel Arnaud will provide testimony and opinions consistent with his knowledge, experience, duties and responsibilities as a general surgeon and as European Ethicon Medical Director, his clinical experience, his review of literature, and the deposition testimony he has given in litigation concerning Ethicon pelvic mesh.

Dr. Axel Arnaud obtained his medical degree in 1978, and completed his residency in surgery for general and digestive surgery in 1984 at the University of Marseille. Dr. Arnaud was an assistant professor of anatomy from 1979-1981 and an assistant professor of general and digestive surgery from 1984-1988. Dr. Arnaud was a practicing surgeon in France until he joined Ethicon in 1992. Dr. Arnaud held the positions of Director of Research and Development until 1999, Scientific Director for Ethicon Europe until 2001, Scientific Director for Gynecare Europe until 2008, Medical Affairs Director for Ethicon EMEA until 2013, and he is currently the Medical Affairs Group Director for Global Surgery EMEA.

As a practicing clinician, Dr. Arnaud was responsible for benefit/risk analyses regarding medical devices. His duties as a European medical director for Ethicon further included making benefit/risk analyses of devices including Prolift, assessing clinical literature, and providing medical input on the Instructions for Use (IFU) and other Ethicon documents needing medical affairs' input and copy review approval.

Dr. Arnaud's surgical experience, review of medical literature, experience with cadaver labs, review of POP procedures, and consultations with other experts in POP repair has given him the expertise to identify the appropriate indications, procedural steps, warnings and adverse events that would be associated with Prolift, and he is expected to testify that the Prolift IFUs were appropriate.

Based in part on his involvement as a Medical Director at Ethicon with the TVM group, Dr. Arnaud is expected to provide testimony as to Ethicon's basis for manufacturing and selling Prolift. More specifically, POP is a prevalent condition that can severely affect a woman's quality of life and Ethicon desired to provide a product that would help women, as the nonsurgical procedures were not sufficient to treat more severe prolapses. Dr. Arnaud will testify about his creation of the History of Prolift documents capturing the history of the development of Prolift. The surgical procedures available to treat POP prior to transvaginal mesh kits (which included Prolift) were abdominal sacrocolpopexy (ASC), colporrhaphy, sacrospinous ligament fixation (SSL) and other native tissue repairs. Dr. Arnaud will testify that native tissue repairs including colporrhaphy and SSL were associated with higher recurrence rates and complications rates similar to transvaginal meshes including Prolift. Further, ASC was more morbid, lead to longer recovery, an increased risk of more severe complications, and similar complication rates to transvaginal meshes including Prolift. Dr. Arnaud may also provide testimony regarding other POP procedures and why Prolift was an important and appropriate treatment option compared to other POP surgical options. Dr. Arnaud will provide the history of the development of the Prolift and his specific personal involvement with the TVM group, including that which predated the launch of Prolift. Prior to Prolift surgeons had used mesh since the 1950s for hernia repair and free cut mesh with abdominal and transvaginal repairs for decades as well. In the early 2000s, a group of French surgeons, called the TVM group investigated a standardized way to place a pre-shaped mesh. With their clinical experience performing pelvic floor surgery and review of literature on the placement of various types of mesh and surgical techniques to place mesh transvaginally, the

TVM group chose Gynemesh PS as the mesh because of its large pore polypropylene properties, and they chose the route based upon the route being previously used successfully.

The TVM group along with surgeons from the United States performed clinical studies (TVM studies) which showed the Prolift was safe and effective. Dr. Arnaud is expected to testify concerning the basis for and clinical support for Ethicon selling Prolift. Dr. Arnaud is expected to testify regarding the subsequent studies that he reviewed as an Ethicon medical director continuing to show the safe and effective use of Prolift and a positive benefit to risk profile.

Dr. Arnaud will testify that there are several randomized controlled trials and long term studies on Prolift and other transvaginal mesh kits which concluded that Prolift is safe and effective, that the complications rates are similar to other non-mesh repairs and have better success rates. Further, that Prolift was one of the most studied mesh kits. The studies further showed improvements in quality of life following Prolift surgery as frequently occurring. Dr. Arnaud was one of Ethicon's physicians who provided medical input for the IFU. The medical portion of the IFU is written for physicians with the input of physicians. Dr. Arnaud will testify that physicians must use their training, experience and education when reading an IFU and when implanting Prolift or any other device.

Dr. Arnaud will testify from a medical perspective regarding the development of the Instructions for Use (IFU), and he is expected to opine that the Prolift IFU was appropriately written.

Dr. Arnaud is expected to provide testimony regarding the adequacy of the contraindication, warnings, the adverse reactions, and actions sections. Further, Dr. Arnaud

will testify that the IFU is intended to identify the specific adverse reactions that may occur from Prolift, and he will opine that the Prolift IFU did so. Dr. Arnaud will further testify that chronic pain and dyspareunia are symptoms of the adverse reactions listed, are warned of, and that such symptoms are common knowledge to surgeons performing surgical POP repairs as pain and dyspareunia can occur with any POP surgery and that such symptoms occur just as frequently with other POP surgical repairs. Dr. Arnaud will also testify about how the IFU was not the only document that Ethicon made available to surgeons, as risks were also discussed and included in Ethicon's professional education materials.

Dr. Arnaud is expected to testify regarding complication rates and success/failure rates for Prolift, as well as the tissue reaction, integration, contraction, infection and compliance of mesh in-vivo. Dr. Arnaud may testify that the tissue reaction has been shown to be appropriate in both human and animal trials, that the Prolift mesh integrates well in the body, that contraction rates are uncommonly clinically significant, and that Prolift is appropriately compliant in the body. Dr. Arnaud will further testify that degradation, if it exists, is not clinically significant and there are not studies to show degradation, even if it were to exist, causes any harm to patients.

6. **Thomas Barbolt**

Defendants' Fact Witness – Principle Scientist and Research Fellow at Ethicon

Videotaped Testimony

Estimated Time of Testimony – 45 minutes.

Substance of Testimony – *See* below

Defendants will present Dr. Thomas Barbolt through his designated deposition testimony, which was previously disclosed to Plaintiff in this action. Dr. Barbolt was a principle scientist and research fellow at Ethicon from 1995 to 2008, and he was responsible for testing the various polymers and materials used in Ethicon's pelvic mesh devices. Dr. Barbolt will testify that polypropylene, one of the materials used in Ethicon's PROLENE Soft Mesh, is biocompatible, safe, and is not associated with degradation, particle loss, or excessive fibrosis and inflammation. Dr. Barbolt will also testify that PROLENE and PROLENE Soft has been extensively tested in animals and has been safely implanted in the body for decades.

Thomas A. Barbolt, Ph.D., D.A.B.T., toxicologist and experimental pathologist and former Ethicon Scientist and Research Fellow, is expected to testify consistent with his testimony given in litigation concerning Ethicon pelvic mesh. Dr. Barbolt may also testify regarding the pathology, toxicology, preclinical and biomaterial science and biocompatibility of implants, mesh, polymers, polypropylene, and Prolift, the testing and safety of these materials, and rebuttal of issues raised by plaintiff. Dr. Barbolt received his B.S. in Biology from LeMoyne College in 1972, and a Ph.D. in Experimental Pathology and Toxicology from Albany Medical College in 1978. He has been certified in Toxicology by the American Board of Toxicology from 1981 through 2011, and has attended over 75 post-graduate continuing education courses in the fields of pathology or toxicology. Dr. Barbolt has published 74 abstracts and/or publications in peer-reviewed journals relating to colon carcinogenesis, animal models of human disease, the toxicologic pathology of a variety of pharmaceutical and biotechnology products, and implantable medical devices. Dr. Barbolt has been a member of the International Standards Working Groups for ISO 10993 and developed Guidelines for the

Biological Evaluation of Medical Devices. This included ISO10993 Part 6 that addresses tests for local effects of devices after implantation and ISO 10993 Part 17 that addresses the establishment of allowable limits for leachable substances from medical devices.

Dr. Barbolt will provide testimony that polypropylene, one of the materials used in Ethicon's Prolene Mesh, is biocompatible, safe and the most widely used material in the body for the treatment of incontinence, pelvic organ prolapse and repair of hernias. Dr. Barbolt will further testify that Prolene Mesh consists of polypropylene plus the addition of five proprietary additives that Ethicon adds during the manufacturing process of its Prolene fiber used to construct the mesh. Two of these additives are anti-oxidants used to prevent oxidation, the chemical process by which some of Plaintiff's experts allege Prolene Mesh degrades. Ethicon's addition of the additives, including the two anti-oxidants, is what makes Prolene Mesh chemically different from any other manufacturer's mesh on the market. Dr. Barbolt may testify that Prolene has been extensively tested in animals and safely implanted in the body for decades.

Dr. Barbolt will provide testimony that other polymers have not shown themselves to have superior biocompatibility for the treatment of stress urinary incontinence. Dr. Barbolt may provide testimony regarding other meshes Plaintiff's experts may allege are superior to Prolene Mesh. Dr. Barbolt may provide testimony regarding the fibers, structure, strength and pore sizes of Prolene mesh.

Dr. Barbolt may provide testimony regarding the biological or foreign body response to implants. Dr. Barbolt may testify that an inflammatory response occurs when Prolene Mesh is implanted in vivo, which is necessary for tissue incorporation and the tissue appropriately incorporates through the pores and around the fibers of Prolene Mesh and does not encapsulate

the implant with scar tissue. The inflammatory response and tissue integration for Prolene Mesh was studied by Ethicon in animals and the mesh is considered appropriate for clinical use.

Dr. Barbolt will provide testimony regarding the test results and studies he performed and reviewed while at Ethicon that demonstrate the ability of the body's immune system to respond to bacterial inoculation on the surface of Prolene Mesh following its implantation.

Dr. Barbolt may provide testimony regarding the appropriateness of Ethicon's biocompatibility testing for Prolene Mesh, and that Prolene Mesh used in Prolift is biocompatible. Dr. Barbolt will provide testimony regarding Ethicon's testing for toxicity of Prolene Mesh, and that it is nontoxic. Dr. Barbolt may provide testimony that the Prolene Mesh used in Prolift is not carcinogenic, that there is no peer reviewed medical literature proving it is carcinogenic and that Ethicon conducted appropriate tests to establish that it is not carcinogenic. Dr. Barbolt may testify that Prolene Mesh has sufficient space for tissue integration and pre-clinical studies show good tissue integration. Dr. Barbolt will provide testimony that Prolene Mesh does not leach substances that would be harmful to the human body. Dr. Barbolt will provide testimony that Prolene Mesh does not exhibit particle loss in vivo, and that even if it did, such in vivo particles would have no adverse clinical effect since such particles would also be made of Prolene polypropylene.

Additionally, Dr. Barbolt may testify that Prolene Mesh is considered inert and that it does not degrade in vivo to any appreciable extent. Dr. Barbolt may testify that degradation implies a loss of molecular weight and physical properties, such as tensile strength, and that Ethicon's testing, including the 7-year Dog Study, showed no significant loss of molecular

weight or physical properties after seven years. Dr. Barbolt will further testify that even if surface degradation occurs over time, which is posited by some Plaintiff's experts, that such degradation would not be considered clinically significant because the mesh would already be integrated with surrounding tissue and the mesh itself is not known to fail clinically from loss of strength.

7. Scott Ciarrocca

Defendants' Fact Witness – Engineer for Ethicon

Live Testimony

Estimated Time of Testimony – 3 hours.

Substance of Testimony – *See* below

Scott Ciarrocca is a biomedical engineer that has worked at Ethicon since 1997. He will testify about his background, education, and experience.

Mr. Ciarrocca will testify about his work as a biomedical engineer in the medical device industry. He will testify about all of the tools, approaches, and techniques biomedical engineers use to safely develop medical devices.

Mr. Ciarrocca will explain that medical devices contain inherent risks. He will explain that it is impossible to eliminate all risks from these devices. He will explain to the jury the methods by which Ethicon and other manufacturers attempt to reduce these risks. He will also explain how Ethicon educates the users of its products on the risks that cannot be eliminated. He will explain that for medical devices such as Prolift that the end user is a board-certified physician. He will explain how the knowledge, training, and experience of a board-certified physician is the predicate for Ethicon's educational programs that taught surgeons how to

implant the Prolift. He will further explain that Ethicon is not required to warn board-certified surgeons of commonly known risks.

Mr. Ciarrocca will explain that erosion is a known risk of all surgically implantable materials, including Prolene mesh. He will also explain that a fistula is a known risk of all pelvic floor surgeries. Mr. Ciarrocca will explain that Ethicon warned about both of these risks. Mr. Ciarrocca will explain the ways that Ethicon attempted to reduce the incidence of exposures with Prolift and all efforts in that regard. Ultimately, it was impossible to eliminate the risk of exposure with Prolift because all surgically implantable materials present the risk of exposure or erosion.

Mr. Ciarrocca will talk about the standards that govern the development of medical devices. These standards include internal standards at Ethicon, ISO standards, and federal governmental regulations. Mr. Ciarrocca will explain that the medical device industry is one of the most heavily regulated industries. He will explain that the development of medical devices is governed by these relevant standards and that medical devices cannot be sold unless they comply with these standards.

Mr. Ciarrocca will testify about Prolene. He will explain to the jury that Prolene has been safely used in the human body since Prolene sutures were approved by the FDA pursuant to a New Drug Application ("NDA") in 1969. Since that time, Prolene has been used in numerous areas of the body when surgeons need a permanent material to augment a repair. He will testify about how this half- century of safe use in the body confirmed Ethicon's belief that Prolene was safe for implantation. He will talk about the development of Prolene sutures, Prolene mesh, and products that use Prolene mesh, like Prolift and TVT.

Mr. Ciarrocca will also testify that Prolene has been subjected to testing on numerous occasions to determine its biocompatibility. He will testify to the results of those tests and explain how these results affected Ethicon's belief that Prolene is safe for implantation in the human body. Mr. Ciarrocca has vast experience in the testing of medical devices, and he will explain all of the tests to which they are subjected, the reasons behind the tests, and the ISO standards that govern these tests. He will explain that Prolift and Prolene Soft mesh passed all such tests.

Mr. Ciarrocca will testify regarding Ethicon and its various products that have improved women's health. These products have included Prolift and the TVT platform of anti-incontinence products. Mr. Ciarrocca will explain how the success of the TVT platform led to Ethicon's study of ways to safely use Prolene mesh in other areas of the pelvic floor.

Mr. Ciarrocca was the R&D project lead for Prolift and was responsible for maintaining the Design History ("DHF") file, among other things. He will introduce documents into evidence from the DHF to show that Ethicon followed industry standards when designing Prolift.

Mr. Ciarrocca will explain how Ethicon uses a cross-functional team to design medical devices. He will explain the various members of the cross-functional team that developed and launched Prolift.

Mr. Ciarrocca will testify about the early development of Prolift, including work performed by the French surgeons who initially developed the product (the "TVM group") and the studies, development activities, labeling, and physician training that occurred in the United States. He will explain that the TVM Group took surgeries that had been performed for

decades and made these surgeries consistent, standardized, and safer for their patients. He will explain that these surgeons chose Gynemesh Prolene Soft mesh for their technique because they got the best results when they used Prolene Soft mesh in their procedure with their patients. He will testify about Ethicon's reliance on the TVM group's clinical results and additional clinical studies and evaluations performed by Ethicon that led Ethicon to believe Prolift was safe.

Mr. Ciarrocca will testify that materials like Vypro were found to be unsuitable for the pelvic floor. Mr. Ciarrocca will testify that, at the time of Ms. Smith's surgery, there was insufficient clinical evidence that Ultrapro could be used in Prolift.

Mr. Ciarrocca will testify about all of the steps that Ethicon took to bring Prolift to market. He will further testify about how each of these steps met best engineering practices and were consistent with internal procedures, ISO standards, and federal regulation.

Mr. Ciarrocca will testify about the biocompatibility and risk assessments performed on the Prolift; Ethicon's product design processes in general and the specific tasks performed for Prolift; communications with the French surgeons who invented the product regarding mesh type and shape; cadaver labs assessing the safety and functionality of the product; clinical studies relied on by the company to assess product safety; the feasibility of alternative designs; the Clinical Expert Report prepared by the company; and the tool system designed by Ethicon for placement of the Prolift.

Mr. Ciarrocca will testify regarding the development of the cannulas used for Prolift.

Mr. Ciarrocca will testify that Prolift was not "rushed to market." On the contrary, he will explain that Ethicon worked on the project for many years prior to its launch, working with the TVM Group and US physicians.

Mr. Ciarrocca will testify about the work that Ethicon did to validate the IFU. This will include the interviews it conducted with surgeons to ensure the IFU was adequate for their needs. These interviews included questions about whether the IFUs adequately conveyed the risks of Prolift. He will explain that the Prolift IFU was developed by a cross-functional team that included the medical directors that oversaw the development of Prolift.

Mr. Ciarrocca will testify that there was no safer alternative design at the time of Ms. Smith's surgery. Mr. Ciarrocca will testify that if Ethicon thought there was a safer alternative design that Ethicon would have adopted it and brought it to market.

Mr. Ciarrocca will testify about Ethicon's professional education program and why the company engaged in this program.

8. Piet Hinoul

Defendants' Fact Witness – Worldwide Medical Director for Ethicon

Videotaped Testimony

Estimated Time of Testimony – 2.5 hours.

Substance of Testimony – *See* below

Defendants will present Dr. Piet Hinoul through his designated deposition testimony, which was previously disclosed to Plaintiff in this action. Dr. Hinoul joined Ethicon as the Worldwide Medical Director in 2008, and his responsibilities included evaluating the safety and effectiveness of Ethicon's pelvic mesh products, including the Prolift, until he left Ethicon

in early 2020. Specifically, Dr. Hinoul will testify regarding his knowledge, experience, duties and responsibilities as a urogynecologist and Ethicon Medical Director, as well as his clinical experience and review of literature related to the Prolift device.

Dr. Hinoul also had responsibility for evaluating the safety and effectiveness of Ethicon's pelvic mesh products, including the TVT family of devices, until he left Ethicon in early 2020. Dr. Hinoul will testify regarding the safety and effectiveness of mid-urethral slings like the TVT-O, including a review of medical literature and studies supporting their safety and effectiveness.

Dr. Piet Hinoul will provide testimony and opinions consistent with his knowledge, experience, duties and responsibilities as an urogynecologist and Ethicon Medical Director, as well as his clinical experience, review of literature, and the deposition and trial testimony he has given in litigation concerning the safety and efficacy of Ethicon's pelvic mesh that he has reviewed as part of his role as Medical Director.

Dr. Hinoul is a trained urogynecologist who has implanted many Prolift devices, has performed many Pelvic Organ Prolapse (POP) procedures, and has provided training and been involved with the training on the POP products. While a clinician, Dr. Hinoul's clinical practice included the repair of prolapse and pelvic floor repairs for women. He has been an author on publications involving POP meshes. His duties as medical director included benefit/risk analyses of devices, drafting clinical evaluation reports, assessing clinical and medical literature, assessing Ethicon funded studies, speaking at panel meetings, reviewing adverse events, new product development, corresponding with physicians regarding the use of incontinence and pelvic floor products and providing medical input on the Instructions for Use

(IFU), patient brochures, professional education, design verification materials, and other Ethicon documents needing medical affairs' input.

Dr. Hinoul was trained on prolapse repairs including the Prolift devices, and the associated benefits and risks. In addition to this training, Dr. Hinoul has performed many POP repairs, including Prolift, has kept apprised of the literature on Prolift and other POP repairs, and has reviewed adverse event reports for these and other pelvic floor procedures. Dr. Hinoul has also been involved with the development of IFUs from a medical perspective as a medical director for Ethicon. As a result, Dr. Hinoul knows the appropriate indications, procedural steps, warnings and adverse events that would be associated with Prolift, and he is expected to testify that the Prolift IFU is appropriate.

As a practicing urogynecologist and as medical affairs director for Ethicon, Dr. Hinoul has personally determined that the benefits of Prolift outweigh the risks. In reaching this determination, he relied upon his clinical experience, training, education, cadaver labs, his review of the applicable literature and the documents that led to the launch of Prolift. In his role as medical affairs director, building on his clinical experience, Dr. Hinoul has prepared clinical expert reports on Prolift and has provided medical advice on the benefit/risk assessment of Prolift, including the preparation of company documents reflecting his benefit/risk assessment. Dr. Hinoul will testify that in accordance with his knowledge, education, training, investigation and evaluation as part of his duties to review the safety performance of Ethicon's prolapse devices, the medical literature and his clinical experience that Prolift was a safe and effective device to treat pelvic organ prolapse.

Dr. Hinoul is expected to provide testimony as to Ethicon's basis for manufacturing and selling Prolift as well as the historical background of the TVM group and his involvement with the TVM group in continuing to evaluate the Prolift as part of his duties at Ethicon. More specifically, POP is a prevalent condition that can severely affect a woman's quality of life and Ethicon desired to provide a product that would help women, as the nonsurgical procedures were not sufficient to treat more severe prolapses. Dr. Hinoul will discuss the safety and efficacy of alternative procedures available to treat prolapse, including abdominal sacrocolpopexy (ASC), sacrospinous ligament fixation (SSL), and other native tissue repairs, and how they compared to Ethicon's POP transvaginal mesh kits (which included Prolift). Dr. Hinoul will testify that in evaluating the medical literature as part of his role at Ethicon, native tissue repairs including colporrhaphy and SSL were associated with higher recurrence rates and complications rates similar to transvaginal meshes including Prolift. Further, ASC was more morbid, lead to longer recovery, an increased risk of more severe complications, and similar complication rates to transvaginal meshes including Prolift. Dr. Hinoul may also provide testimony regarding other POP procedures and why Prolift was an important and appropriate treatment option compared to other POP surgical options. Further, Dr. Hinoul may further testify regarding the degrees of POP and how they are scaled including POP-Q and other methods, and why Ethicon did not provide specific contraindications for degree of prolapse in the IFU.

Prior to Prolift surgeons had used mesh since the 1950s for hernia repair and free cut mesh with abdominal and transvaginal repairs for decades as well. In the early 2000s, a group of French surgeons, called the TVM group, investigated a standardized way to place a pre-

shaped mesh. With their clinical experience performing pelvic floor surgery and review of literature on the placement of various types of mesh and surgical techniques to place mesh transvaginally, the TVM group chose Gynemesh PS as the mesh because of its large pore polypropylene properties, and they chose the route based upon the route being previously used successfully.

The TVM group along with surgeons from the United States performed clinical studies (the TVM studies) which he has reviewed and analyzed both before coming to Ethicon and in his role as an Ethicon medical director, which showed the Prolift was safe and effective. Dr. Hinoul is expected to testify regarding the calculation and determinations of the TVM's data concerning erosion rates, POP-Q scales, recurrence rates, other outcomes.

Dr. Hinoul is expected to testify concerning the basis for and clinical support for Ethicon selling Prolift. Dr. Hinoul is expected to testify regarding his duties as Medical Director to review the medical literature on an ongoing basis to evaluate the safety and efficacy of Ethicon's POP devices. Dr. Hinoul will testify as to his findings from his review of medical literature from the standpoint of his role as Medical Director and his findings that Ethicon's POP devices continued to demonstrate the safe and effective use of Prolift and a positive benefit to risk profile. As part of his duties to review medical literature at Ethicon, Dr. Hinoul will testify that there are several randomized controlled trials and long term studies on Prolift and other transvaginal mesh kits which concluded that Prolift is safe and effective and further, that Prolift was one of the most studied mesh kits. The studies also showed improvements in quality of life and patient satisfaction following Prolift surgery.

Dr. Hinoul came to Ethicon shortly before publication of the 2008 Public Health Notice and he spoke at the September 2011 FDA Advisory Committee hearings following publication of the 2011 Public Health Notice. He may provide testimony regarding Ethicon's responses to such Public Health Notices and 522 Orders.

In Dr. Hinoul's position as medical affairs director for Ethicon, his job responsibilities included providing medical input for the IFU. The medical portion of the IFU is written for physicians with the input of physicians. Dr. Hinoul will testify that physicians must use their training, experience and education when reading an IFU and when implanting Prolift or any other device. Dr. Hinoul will testify from a medical perspective regarding the development of the Instructions for Use (IFU), and he is expected to opine that the Prolift IFU was appropriately written as to the sections for: indications, procedural steps, warnings, adverse reactions, contraindications and actions. Dr. Hinoul will further testify that the IFU is not intended to be a comprehensive guide for surgical treatment because it is for surgeons who are trained to treat POP and who must use their training, experience and education in conjunction with the procedural steps provided in the IFU. As part of his role in evaluating the adequacy of IFUs, Dr. Hinoul will also discuss complications that were considered to be commonly known to pelvic floor surgeons performing prolapse repairs.

Dr. Hinoul will provide testimony regarding the procedural steps for Prolift and the reasons why the procedural steps were provided as they were. He will also provide testimony as to how Ethicon instructed physicians to place the Prolift mesh.

Dr. Hinoul will provide testimony regarding his role as Medical Director in assessing the adequacy of the contraindication, warnings, the adverse reactions, and actions sections of

the POP device Instructions For Use, including the various versions of the Prolift IFUs. He will specifically provide testimony as to why specific warnings and adverse reactions were or were not provided. Further, Dr. Hinoul will testify that the IFU is intended to identify the specific adverse reactions that may occur from Prolift, and he will opine that the Prolift IFU did so. Dr. Hinoul will further testify that chronic pain and dyspareunia are symptoms of the adverse reactions listed, are warned of, are discussed and warned of in Ethicon professional education and the Prolift Surgeons Resource Monograph which supplements the IFU, and that such symptoms are common knowledge to surgeons performing surgical POP repairs as pain and dyspareunia can occur with any POP surgery and that such symptoms occur just as frequently with other POP surgical repairs.

In Dr. Hinoul's position as medical affairs director he is sometimes called upon to participate in the copy-review of patient brochures and other marketing material and provide input from a medical perspective. Dr. Hinoul may give testimony regarding the accuracy and appropriateness of such documents and the use of patient brochures from a medical perspective.

Prior to coming to Ethicon, Dr. Hinoul served as a professional education preceptor for Ethicon. In that position, Dr. Hinoul trained physicians on pelvic floor surgery using mesh products. Thereafter, in his role as medical affairs director, Dr. Hinoul became further involved with Ethicon's professional education program. His responsibilities in that regard involved reviewing professional education material to ensure its accuracy and appropriateness, and to facilitate education. Relying upon this knowledge and experience, Dr. Hinoul may provide testimony regarding Ethicon's professional education program, the procedural steps, clinical literature, IFU, the Prolift Surgical Technique Guide, the Prolift Surgeons Resource

Monograph, complications, success rates, and any other medical portions of the professional education provided for Prolift. Dr. Hinoul will further testify regarding the different phases of the professional education program, including didactic lectures, cadaver labs, preceptorships and proctorships. He may further offer testimony and opinions from the perspective of a professional education trainer prior to coming to Ethicon. Such testimony may specifically include the adequacy of Ethicon's professional education training including the conveyance of risks and complications and the treatment of them in the professional education. Dr. Hinoul may also provide testimony on yearly Summits. Dr. Hinoul may testify about the reasons Ethicon consulted with key opinion leaders to help provide instruction to other surgeons on the safe and efficacious use of Prolift and other devices.

In his role as medical affairs director, Dr. Hinoul was apprised of the certificates that were provided to professional education trainees, and he will testify that these certificates were simply acknowledgments of attendance and not a certification of the physician's ability to perform the surgery. Dr. Hinoul will further opine that it is the surgeon's responsibility to determine whether he or she is capable of performing any surgery, and that credentialing takes place by professional organizations or hospitals, not by Ethicon or other manufacturers.

In Dr. Hinoul's role as a medical director and as a physician, he will discuss the company's knowledge and reasoning for the anatomical placement of Ethicon's POP devices, and the safe distances that were known based on pelvic anatomy. Dr. Hinoul may testify about how the passage of Prolift trocars were an improvement to how surgeons were previously placing mesh. Dr. Hinoul may offer testimony and opinions about the design of Prolift and how it safely traverses the pelvic floor anatomy and nerves. Dr. Hinoul was also personally

involved in the continued studies of Prolift such as the TVM studies as well as other potential new meshes for POP.

Dr. Hinoul may provide testimony regarding the use of UltraPro or Prolift+M and other meshes like Vypro. Specifically, Dr. Hinoul may testify as to the trial of Vypro by the TVM Group which in 2004 reported that Vypro showed poor tolerance, and as to the development of Prolift+M, the reasons why it was developed, the timing of it being launched and the reasons why UltraPro was not initially used in the Prolift. Dr. Hinoul may also discuss the clinical trials on Prolift+M and the results of such studies. Specifically, that the short and long term studies did not show the Prolift+M was safer or more effective than Prolift. Dr. Hinoul will also testify that no other procedure for repairing POP surgically was safer and more effective than Prolift for certain patients. Dr. Hinoul will further testify on behalf of Ethicon's medical affairs as to why Ethicon continued to use the Gynemesh PS in Prolift. Based upon Dr. Hinoul's review of literature, his experience at Ethicon and his clinical experience, he will testify Prolift was a safe and effective option when he joined Ethicon as Medical Director, and literature after this time continued to support such a conclusion.

Based on his role as Medical Director in interacting with design engineers and end-users of Ethicon's POP devices, Dr. Hinoul may provide testimony with regard to the pore size and weight of mesh in Prolift, including the other material characteristics of other meshes on the market to show that the mesh used by Ethicon was necessary, safe and effective.

Additionally, in his role as medical affairs director, Dr. Hinoul assessed the tissue reaction, integration, contraction, infection and compliance of mesh in-vivo, and is expected to provide testimony about his and Ethicon's analysis of each and why Prolift was safe. Dr.

Hinoul may testify that the tissue reaction has been shown to be appropriate in both human and animal trials, that the Prolift mesh integrates well in the body, that contraction rates are uncommonly clinically significant, and that Prolift is appropriately compliant in the body.

Dr. Hinoul also assessed complication rates and success/failure rates for Prolift while at Ethicon. Dr. Hinoul may therefore testify about the adverse reactions that are associated with Prolift and other surgical procedures to show why Ethicon believed that the benefits of Prolift outweighed the risks. Dr. Hinoul will also testify, based upon his clinical practice and review of the adverse event reports, company studies and literature, as to the rate of occurrence of adverse events and success/failure rates, and why he believes that the benefits outweigh the risks. Dr. Hinoul is expected to provide testimony regarding exposure/erosion rates and the treatment of such exposures or any other complication. More specifically he is expected to testify that some of the exposures can be treated conservatively or with no treatment at all, while other patients may need to have a small portion of the mesh excised. Dr. Hinoul will testify that it is uncommon that the whole of the mesh or large portions need to be taken out. Dr. Hinoul will further testify about Ethicon's evaluation of degradation and that degradation, if it exists, is not clinically significant and there are not studies to show degradation, even if it were to exist, causes any harm to patients.

Dr. Hinoul may also testify, from a design perspective, to any design documents for Prolift, or any other topic on which he has been identified as a corporate witness on behalf of Ethicon.

9. Vincent Lucente

Defendants' Fact Witness – Ethicon Consultant

Videotaped Testimony

Estimated Time of Testimony – 1.2 hours.

Substance of Testimony – *See* below

Defendants will present Dr. Vince Lucente through his designated deposition testimony, which was previously disclosed to Plaintiff in this action. Dr. Lucente is practicing urogynecologist in Pennsylvania and former consultant at Ethicon. Specifically, Dr. Lucente will provide testimony and opinions consistent with his knowledge, experience, duties and responsibilities as an urogynecologist and Ethicon consultant for professional education and training, as well as his clinical experience, review of literature, and the deposition and trial testimony he has given in litigation concerning Ethicon pelvic mesh, including the Prolift. Moreover, Dr. Lucente will testify about his personal involvement in the launch of the Prolift device, training surgeons on using Prolift, and his own clinical experience implanting Prolift in his patients.

Dr. Vincent R. Lucente will provide testimony and opinions consistent with his knowledge, experience, duties and responsibilities as an urogynecologist and Ethicon consultant for professional education and training, as well as his clinical experience, review of literature, and the deposition and trial testimony he has given in litigation concerning Ethicon pelvic mesh. Dr. Lucente obtained his medical degree in 1989. After graduation, he attended a residency program in obstetrics and gynecology at North Shore University Hospital in Indiana for two years. Dr. Lucente has been board certified in obstetrics and gynecology since 1992, and has been practicing urogynecology for over 20 years. From 1990 to 1993, he served as a clinical assistant professor in Obstetrics and Gynecology at Cornell University Medical

College, ran a private practice in General Obstetrics and Gynecology, and was the Physician-in-Charge of Urogynecology at North Shore General Hospital. In 1993, he joined the LeHigh Valley Health Network, where over a nine year span, he served as Chief of both the Division of Gynecology and Section of Urogynecology and Reconstructive Pelvic Surgery, Vice Chair of Education and Research, and Medical Director of the Women's Health Team.

From 2002-2008, he served as Chief of the Section of Female Pelvic Medicine and Reconstructive Surgery in the department of Obstetrics and Gynecology at Abington Memorial Hospital. Concurrently, he also served as the Medical Director at the Pelvic Health Center in St. Luke's University Health Network from 2005-2010. Currently, Dr. Lucente serves as Chief of Gynecology at St. Luke's University Health Network, Partner and Chief Medical Officer of the Institute for Female Pelvic Medicine and Reconstructive Surgery, and Clinical Professor of Obstetrics and Gynecology at Temple University College of Medicine.

Dr. Lucente is a trained urogynecologist who has implanted many Prolift devices, has performed many Pelvic Organ Prolapse (POP) procedures, and has provided training and been involved with the training on the POP products. As a clinician, Dr. Lucente's clinical practice includes the repair of prolapse and pelvic floor repairs for women. He has been an author on publications involving POP meshes. Dr. Lucente has performed all different types of prolapse surgeries over the years, including but not limited to native tissue repair using traditional standard approaches to the vagina and standard surgical equipment, endoscopic repairs via a minimally invasive approach transabdominally, suture based repairs, with or without graft augmentation, and synthetic material repairs, using a transvaginal route, transabdominal route, and transabdominal via endoscopic route.

Dr. Lucente's surgical experience, review of medical literature, experience with cadaver labs, review of POP procedures, and consultations with other experts in POP repair has given him the expertise to identify the appropriate indications, procedural steps, warnings and adverse events that would be associated with Prolift, and he is expected to testify that the Prolift IFU is appropriate.

Dr. Lucente is also expected to provide testimony as to the necessity in the medical field for Ethicon manufacturing and selling Prolift. More specifically, POP is a prevalent condition that can severely affect a woman's quality of life and Ethicon desired to provide a product that would help women as the nonsurgical procedures were not sufficient to treat more severe prolapses. The surgical procedures available to treat POP prior to transvaginal mesh kits (which included Prolift) were abdominal sacrocolpopexy (ASC), colporrhaphy, sacrospinous ligament fixation (SSL) and other native tissue repairs. Dr. Lucente will testify that native tissue repairs including colporrhaphy and SSL were associated with higher recurrence rates and complications rates similar to transvaginal meshes including Prolift. Further, ASC was more morbid, lead to longer recovery, an increased risk of more severe complications, and similar complication rates to transvaginal meshes including Prolift. Dr. Lucente may also provide testimony regarding other POP procedures and why Prolift was an important and appropriate treatment option compared to other POP surgical options.

More specifically, Dr. Lucente will also opine on how he views the ASC as more invasive than the Prolift procedure. He will testify that because the vagina is natural orifice, going through it to gain entry into a vital organ is better and minimally invasive. He will further testify that ASC also poses more risks: ileus, potential spontaneous rupture; infection; and

potential loss of spinal disks. ASC almost always requires general anesthesia while it is almost never needed with a Prolift procedure. He will testify that general anesthesia creates pulmonary risks and injury to pre-sacral vessels, which can result in life-threatening hemorrhaging and exposures after ASC. Lucente will further opine that the Prolift procedure is more fluent, more time efficient, and more proficient.

Dr. Lucente will also provide the history of the development of the Prolift and his specific personal involvement as a consultant with the TVM group, including that which predated the launch of Prolift. Dr. Lucente may testify about his involvement in the Gynemesh PS vaginal vs. abdominal study that helped Ethicon assess the safety of the transvaginal placement of Gynemesh PS. Prior to Prolift surgeons had used mesh since the 1950s for hernia repair and free cut mesh with abdominal and transvaginal repairs for decades as well. In the early 2000s, a group of French surgeons, called the TVM group, investigated a standardized way to place a pre-shaped mesh. With their clinical experience performing pelvic floor surgery and review of literature on the placement of various types of mesh and surgical techniques to place mesh transvaginally, the TVM group chose Gynemesh PS as the mesh because of its large pore polypropylene properties, and they chose the route based upon the route being previously used successfully.

The TVM group along with surgeons from the United States, including Dr. Lucente, performed clinical studies (TVM studies), which showed the Prolift was safe and effective. Dr. Lucente is expected to testify regarding the subsequent studies that he reviewed as an Ethicon consultant, and conducted such as the Prolift IIS study and the separate Prolift

retrospective chart review of over 1,000 patients, to show the safe and effective use of Prolift and a positive benefit to risk profile.

Dr. Lucente will testify that there are several randomized controlled trials and long-term studies on Prolift and other transvaginal mesh kits, which concluded that Prolift is safe and effective. These trials and studies all showed that the complications rates are similar to other non-mesh repairs and have better success rates. Further, he will testify that Prolift was one of the most studied mesh kits and that the studies showed improvements in quality of life as frequently occurring following Prolift surgeries.

Dr. Lucente served as a professional education preceptor for Ethicon. In that position, Dr. Lucente trained physicians on pelvic floor surgery using mesh products. Relying upon this knowledge and experience, Dr. Lucente may provide testimony regarding Ethicon's professional education program, the procedural steps, clinical literature, IFU, complications, success rates, and any other medical portions of the professional education provided for Prolift. Dr. Lucente will further testify regarding the different phases of the professional education program, including didactic lectures, cadaver labs, preceptorships and proctorships. He may further offer testimony and opinions from the perspective of a professional education trainer. Such testimony may specifically include the adequacy of Ethicon's professional education training including the conveyance of risks and complications and the treatment of them in the professional education. Dr. Lucente may also provide testimony on yearly Summits.

In Dr. Lucente's role as a physician, he is an expert on female pelvic anatomy, the devices that should be used in the anatomy, and the appropriate placement of devices in the body. Dr. Lucente may offer testimony and opinions about the design of Prolift and how it

safely traverses the pelvic floor anatomy and nerves. Dr. Lucente was also personally involved in the continued studies of Prolift and the TVM studies as well as other potential new meshes for POP.

Dr. Lucente may provide testimony with regard to the pore size and weight of mesh in Prolift, including the other material characteristics of other meshes on the market to show that the mesh used by Ethicon was safe and effective.

Dr. Lucente also assessed complication rates and success/failure rates for Prolift while in clinical practice. Dr. Lucente may therefore testify about the adverse reactions that are associated with Prolift and other surgical procedures to show why Ethicon believed that the benefits of Prolift outweighed the risks. Dr. Lucente will also testify, based upon his clinical practice and review of the adverse event reports, company studies and literature, as to the rate of occurrence of adverse events and success/failure rates, and why he believes that the benefits outweigh the risks.

With regards to risks, Dr. Lucente will also testify how patients with prolapse experience pain during sexual intercourse and how de novo dyspareunia is a potential complication of any prolapse surgery. He will discuss clinical studies that show the actual rate of dyspareunia goes down after surgery. Through his expertise and experience with the clinical studies, he will further testify that many patients actually restart sexual relations with their husbands and significant others after pelvic reconstructive surgery, after abstaining for intimacy for years. He will testify that patients who abstain from intimacy for years before surgery make it hard, for that particular patient, to quantify dyspareunia before and after surgery. Dr. Lucente will testify that dyspareunia should be broken down into different subsets: (1) the benefit of having

sexual intercourse when a patient could not have it before due to prolapse; (2) the challenges of having discomfort because of the nature of scarring; and (3) the body's healing and reparative process.

Dr. Lucente is also expected to provide testimony regarding exposure/erosion rates and the treatment of such exposures or any other complication. He is expected to testify that some of the exposures can be treated conservatively through hormone therapy and rehabilitation of the vaginal wall, or with small portions of excised mesh. Dr. Lucente will also testify that it is uncommon that the whole of the mesh or large portions need to be taken out. He will further testify that the only unique issue of mesh is the potential risk of mesh exposure and that dyspareunia is a general risk for any vaginal and pelvic surgery. His opinion is that any surgery that is done in the pelvis and close to the vaginal proximity causes pain at that site. Thus, he will testify that dyspareunia is an extremely common event for surgery performed in and around the region on the vagina and around the pelvis.

10. Charlette Owens

Defendants' Fact Witness – Ethicon Medical Director

Videotaped Testimony

Estimated Time of Testimony – 1 hour.

Substance of Testimony – *See* below

Defendants will present Dr. Charlotte Owens through her designated deposition testimony, which was previously disclosed to Plaintiff in this action. Dr. Owens was a Medical Director at Ethicon from 2003 to 2006. Specifically, Dr. Owens will testify regarding her knowledge, experience, duties and responsibilities as an OBGYN and Ethicon Medical

Director, her clinical experience, and review of Prolift literature. Moreover, Dr. Owens will testify about her role in launching the Prolift, including the supporting data that Ethicon relied upon prior to the launch of Prolift, and the continued postmarket surveillance that Ethicon performed to continuously evaluate the device.

Dr. Charlotte Owens was the Worldwide Medical Director at Ethicon from 2003 to 2006, and she responsible for overseeing different aspects of Ethicon's pelvic mesh devices during that time. Dr. Owens will testify regarding the general risks associated with the TVT and TVT-O and the contents of the Instructions for Use for those products.

She is expected to testify consistent with her testimony given in litigation concerning Ethicon pelvic mesh. Dr. Owens may provide testimony and opinions consistent with her knowledge, experience, duties and responsibilities as an OBGYN and Ethicon Medical Director, her clinical experience, and review of literature.

Dr. Owens performed a residency in obstetrics and gynecology. In 2003, Dr. Owens joined Ethicon as the medical affairs director, with responsibilities for pelvic floor repair and incontinence repair products. Her duties as medical director included benefit risk analyses of devices, drafting clinical evaluation reports, assessing clinical literature, reviewing adverse events, and providing medical input on the Instructions for Use (IFU), patient brochures, marketing professional education and design verification materials, and other Ethicon documents needing medical affairs' input.

Dr. Owens was trained on the pelvic anatomy and performed surgery in an around the pelvic floor. As a result, Dr. Owens knows the appropriate indications, procedural steps,

warnings and adverse events that would be associated with Prolift devices and is expected to testify that the Prolift IFU is appropriate.

As an OBGYN and as medical affairs director for Ethicon, Dr. Owens personally determined that the benefits of Ethicon POP devices outweighed the risks. In reaching this determination, she relied upon her clinical experience, training, education, experience with cadaver labs, and her review of the applicable literature and the documents that led to the launch of Prolift, a POP device using the same type of mesh as Gynemesh PS. In her role as medical affairs director, Dr. Owens has prepared clinical expert reports on Prolift and has provided medical advice on the benefit risk assessment of Ethicon's POP devices. Dr. Owens will testify that at the time Prolift was launched it was safe and effective and the current medical literature, adverse event reporting and clinical trials supports her opinion. Dr. Owens will testify about the supporting data that Ethicon relied upon prior to the launch of Prolift, and the continued post-market surveillance that Ethicon performed to continuously evaluate the device.

Dr. Owens is expected to provide testimony as to Ethicon's basis for manufacturing and selling the Ethicon POP devices including but not limited to Prolift. More specifically, with regard to POP, it is a prevalent condition that can severely affect a woman's quality of life and Ethicon desired to provide a product that would help women, as the non-surgical procedures were not sufficient to treat more severe prolapses. The surgical procedures available to treat POP prior to transvaginal mesh kits (which included Prolift) were abdominal sacrocolpopexy (ASC), colporrhaphy, sacrospinous ligament fixation (SSL) and other native tissue repairs. Dr. Owens will testify that native tissue repairs including colporrhaphy and SSL

were associated with higher recurrence rates and complications rates similar to transvaginal meshes including Prolift. Further, ASC was more morbid, lead to longer recovery, an increased risk of more severe complications, and similar complication rates to transvaginal meshes including Prolift. Dr. Owens may also provide testimony regarding other POP procedures and why Prolift or transvaginal meshes were an important and appropriate treatment options.

Dr. Owens may provide testimony on the history of the development of the Prolift and transvaginal mesh devices, including her involvement in the development of Prolift as a Medical Director. Prior to Prolift surgeons had used mesh since the 1950s for hernia repair and free cut mesh with abdominal and transvaginal repairs for decades as well. In the early 2000s, a group of French surgeons, called the TVM group, investigated a standardized way to place a pre-shaped mesh. With their clinical experience performing pelvic floor surgery and review of literature on the placement of various types of mesh and surgical techniques to place mesh transvaginally, the TVM group chose Gynemesh PS as the mesh because of its large pore polypropylene properties, and they chose the route based upon the route being previously used successfully.

The TVM group along with several surgeons from the United States, including Dr. Robinson, performed clinical studies (the TVM studies), which showed the Prolift was safe and effective. Dr. Owens is expected to testify concerning the basis for and clinical support for Ethicon selling Prolift or transvaginal meshes for POP.

In Dr. Owens's position as medical affairs director for Ethicon, her job responsibilities included providing medical input for the IFU. The medical portion of the IFU is written for physicians with the input of physicians. Dr. Owens will testify that physicians must use their

training, experience and education when reading an IFU and when implanting Prolift or any other device. Dr. Owens will testify from a medical perspective regarding the development of the Instructions for Use (IFU), and she is expected to opine that the Prolift IFU was appropriately written as to the sections for: indications, procedural steps, warnings, adverse reactions, contraindications and actions. Dr. Owens will further testify that the IFU is not intended to be a comprehensive guide for surgical treatment because it is for surgeons, who are trained to treat POP, and who must use their training, experience and education in conjunction with the procedural steps provided in the IFU.

Dr. Owens will provide testimony regarding the adequacy of the warnings, the adverse reactions, and actions sections in the Prolift IFU. She will also testify as to why specific warnings and adverse reactions were or were not provided. Further, Dr. Owens will testify that the IFU is intended to identify the specific adverse reactions that may occur from the Prolift device, and she will opine that the Prolift IFU at the time of launch did so. Dr. Owens will further testify that chronic pain and dyspareunia are symptoms of the adverse reactions listed, are warned of and are not specific to the device, and that such symptoms are common knowledge to surgeons performing surgical SUI repairs. Dr. Owens will testify that it is well known that the adverse reactions listed in the IFU could lead to the symptoms of chronic pelvic pain or dyspareunia.

In Dr. Owens' position as medical affairs director she was sometimes called upon to participate in the copy-review of patient brochures and other marketing material and provide input from a medical perspective. Dr. Owens may give testimony regarding the accuracy and appropriateness of such documents from a medical perspective.

Dr. Owens became involved with Ethicon's professional education program. Her responsibilities in that regard involved reviewing professional education material to ensure its accuracy and appropriateness, and to facilitate education. Relying upon this knowledge and experience. Dr. Owens will further testify regarding the different phases of the professional education program, including didactic lectures, cadaver labs, preceptorships and proctorships.

In her role as medical affairs director and as a trainer, Dr. Owens was apprised of the certificates that were provided to professional education trainees, and she will testify that these certificates were simply acknowledgments of attendance and not a certification of the physician's ability to perform the surgery. Dr. Owens will further opine that it is the surgeon's responsibility to determine whether he or she is capable of performing any surgery, and that credentialing takes place by professional organizations or hospitals, not Ethicon or other manufacturers.

In Dr. Owens' role as a medical director and as a physician, she is an expert on female pelvic anatomy, the devices that should be used in the anatomy, and the appropriate placement of devices in the body. Dr. Owens' may offer testimony and opinions about the design of the Prolift devices and how they safely traverse the pelvic floor. Dr. Owens will testify about her involvement in Prolift cadaver labs which helped assess the safety of the anatomic passage.

Additionally, in both her clinical practice and in her role as medical affairs director, Dr. Owens assessed the tissue reaction, integration, contraction and compliance of mesh in-vivo, and determined that the benefits of Prolift devices and Prolene Soft Mesh outweighed the risks. Dr. Owens may testify that the tissue reaction has been shown to be appropriate in both human and animal trials, that the Prolene mesh integrates well in the body, that contraction rates are

low or are not clinically significant and cannot be compared to other more-invasive surgeries, and that Prolift is appropriately compliant in the body.

Dr. Owens may also testify, from a design perspective, to any design documents for Prolift and will testify that Prolift was safe and effective as was pelvic mesh for POP.

11. Daniel Smith

Defendants' Fact Witness – Ethicon Engineering Fellow

Videotaped Testimony

Estimated Time of Testimony – .5 hour.

Substance of Testimony – *See* below

Defendants will present Dan Smith through his designated deposition testimony, which was previously disclosed to Plaintiff in this action. Mr. Smith was an engineering fellow at Ethicon who was involved with the design and development of multiple pelvic mesh devices, including the TVT and TVT-O. Mr. Smith will testify regarding the design and development processes within Ethicon for different medical devices, and how those processes played into the components of these devices, including the TVT-O.

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